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Support to State Reorganisation

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Service Contract N° IPA/2019/410-262

DISCRETIONARY POWERS IN THE LEGISLATION THAT REGULATE ISSUING LICENSES FOR PREFORMING HEALTH ACTIVITIES UPON PUBLIC CALL

REF TO ACTIVITIES 2.1., 2.2. AND 2.3.

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Report Cover Page

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1 INTRODUCTION

INSTRUCTIONS

- 1.1 This this Analytical Report consist of 1.) overview of the current state of play in the area of issuing licenses for performing health activities upon a public call; 2.) identified corruption vulnerabilities when it comes to discretionary powers in issuing these types of licenses; and 3.) recommendations for remedying the discretionary powers in the indicated areas where relevant based on good practices.
- 1.2 In order to be able to assess the current state of play we consulted with the main stakeholders who provided us with the list of applicable regulation as well as we organized interviews to understand application of regulation in practice. In addition, we organized a multistakeholder working group through which we obtained additional recommendations.

FORMS AND STRUCTURE OF THIS REPORT

Form

- 1.3 This is the final report. During our work this report may have been made available to recipients in multiple versions in electronic format. Multiple copies and versions of this report may therefore exist and in the case of any discrepancy the final signed hard copy should be regarded as definitive.

Structure

- 1.4 This report is structured as follows:
 - Executive Summary, Section 2;
 - Overview of the relevant legislation, Section **Error! Reference source not found.**;
 - Current state of play and recommendations, Section 4.



2 EXECUTIVE SUMMARY

2.1 For the purposes of this analysis, a screening of the legal framework for general and special administrative procedures conducted by the Ministry of Health through the Department of Regulatory and Administrative Affairs and through the Committees for the Granting of a License to Work of Health Institutions in a Network for the Performance of Secondary Healthcare Activities has been carried out. The following regulations have been reviewed:

2.2 Laws:

- Law for Health Care (ZZZ)
- General Administrative Procedure Act (ZOUP)
- Law on Organization and Work of State Administration Bodies (ZORODU)
- Electronic Management and Electronic Services Act (ZEUEU)
- Law on Electronic Documents, Electronic Identification and Confidential Services (ZEDEIDU)

2.3 Referenced laws not contained in the document:

- Law on Establishments
- Bond Relations Act
- Health Insurance Act

2.4 Referenced bylaws and other acts not contained in this document:

- Regulation for the network of health care facilities
- Methodology for expressing the criteria for granting a licence to perform health activities in the network of healthcare facilities
- Rules on the necessary space, equipment and professional staff for the establishment, start of work and exercise of health activities in healthcare facilities
- Decision to establish a commission to determine the factual situation by exercising insight into the conditions of space and equipment for the performance of health activities.

2.5 There have been some administrative barriers to digitalization that have been recognized, while the following recommendations are given for overcoming those barriers:

Article	Comment



229 (17)	The word “copy” to be replaced by the word “sample”.
230 (12,19,20)	The circumstances under which the public opening is organized. If it must be physically present then it presents an obstacle to the electronic opening. The proposal is to take good practice of public openings through the electronic public procurement system.
231b (4)	Requires the signing of representatives of bidders in a record sheet. Proposal is to delete the wording after the word “bidding” in the Paragraph (4).
231 (1)	To be added to the sentence: “in electronic form”.
231 (3)	<p>The lease agreement is concluded in writing. After the contract is concluded, the "lessee" delivers it to a notary for solemnization. The proposal is to replace the position with: The signatures of the contracting parties are certified by a notary.</p> <p>We must note, "solemnization" provides the lessee with an executive clause in case of failure to meet the contractual obligations by the lessee. Hence, the authorized proposer of possible changes and additions to the Law on Health Care must take a position on the issue.</p>

- 2.7 In terms of the presence of provisions enabling the discretionary authority of the Minister of Health, the Health Ministry and/or the licensing commission, a total of 12 provisions in four members have been recognized:

Article	Comment
44 (3)	<p>The price list for the cost of health treatment of foreigners is adopted by the Director of the JZU, to which the Minister agrees.</p> <p>The proposal is for the Health minister to adopt a price list that will be uniform for all public healthcare facilities.</p>
229 (7, 8 , 9, 12)	<p>Establishment of a Commission for the Implementation of the Licensing Procedure, established by the Ministry of Interior.</p> <p>The law provided for: organization, members, from which ranks members can be elected. No naming procedure is prescribed (appointment without procedure). The paragraph 10 provides for a conflict of interest-basis for the unsuitability of a member.</p> <p>There is a low/moderate risk of corruption. The lines from which the members of the commission may be selected are determined. The law</p>



	<p>does not provide for criteria outside the affiliation of the order (e.g. employee of the Ministry of Health). The possibility of "favoring" individual employees is open, but it must be determined whether this is a risk to the legality of the procedure through which the commission works to find harmfulness.</p> <p>The proposal is: these questions should be answered by "Rules on criteria for the selection of members of the Commission for the implementation of the procedure for granting a license for the performance of health activities in network of health care facilities" and "Guidance on how to operate and act of the Commission for the implementation of a license procedure for the performance of health activities in the network of health care facilities".</p>
230 (4, 8, 13, 15, 27, 28)	<p>Discretionary powers exist in a free assessment of whether to have: compensation for raising tender documentation, modifications and additions to tender documentation, extension of deadlines, conditionality of bidders with a guarantee, free assessment that bidders be members of the chamber's professions, whether to provide an evidentiary means of ability.</p> <p>The proposal is to adopt a rulebook on the manner and form of submission of the bid and form of request for participation in the procedure for granting a license (relevant for paragraphs (12), (19) and (20).</p> <p>In paragraph (3) it must be prescribed that bidders and candidates themselves bear the cost of providing a sample of tender documentation.</p> <p>As referenced in paragraph (31), the methodology already exists as written by the minister.</p>
231a (2)	<p>Formation of a commission by the Director and on the proposal of the Board of Directors of the JZU It says only from the employee line, there are no criteria for employee status. Specifics for each procedure are edited with an announcement.</p>
231g (1)	<p>A possible amendment to the Law will create the possibility of alternative decision-making, which will also be discretionary for the Commission but must exist – because electronic communication is the party's choice.</p>
Rulebook on	<p>The proposal is to change the word "should" throughout the rulebook and</p>



the necessary space, equipment and professional staff for the establishment, start of work and carrying out healthcare activities	replace it with a more appropriate expression which will unequivocally prescribe whether the conditions are necessary or “desirable”. For example, instead of “should” it should be written “necessary” as terminology already present in the Article 20, Article 25 (2) and Article 26.
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3 OVERVIEW OF THE RELEVANT LEGISLATION

OVERVIEW

3.1 For the purposes of this Report, below is the list of legislation consulted and/or are relevant related to issuing licences in the area of health care (in particular to corruption vulnerabilities identified by the State Agency on Prevention of Corruption).

3.2 Table of relevant legislation that was reviewed:

	Laws	Description
1	Law on safety of the blood supply	1. import and export permit of blood and blood components
2	Law on assisted reproductive technologies (IVF)	1. licensing health institutions for autologous IVF treatment 2. import and export of spermatocides from licensed health institutions 3. license for IVF treatment
3	Law on prohibiting development, production, stockpiling and use of chemical weapons	1. license for production of toxic chemicals and precursors and allowing chemical production for non-prohibited aims 2. permit for import, export, transit and stockpiling of toxic chemicals and precursors
4	Law on protection of the population from infectious diseases	1. license for microbiological laboratories for microbiological examinations of infectious agents 2. identifying institutions which provide anti-rabies protection 3. License for screening and for anonymous unrelated blood testing or other biological materials testing from professional institutions 4. license for vaccination for health institution 5. license for disinfection, disinsection and deratization 6. permit for transfer of deceased who had died of infectious diseases abroad
5	Law on health protection	1. License for introduction of new health technology and equipment, new health methods or interventions in healthcare institutions in network 2. health care institution license to work 3. approving Statute of Law on Health care 4. licensed mentors who organize and monitor the implementation of the plan and program for specializations and sub-specializations 5. prior consent for donations and sponsorships from individuals or legal entities donated to health workers or associates for attending conferences, seminars, and works shops for continuous and professional capacity building 6. license for occasional health practice in various public health institutions for health workers i.e. associates who have been elected state officials pursuant to the law 7. license for uninterrupted health work – on duty in



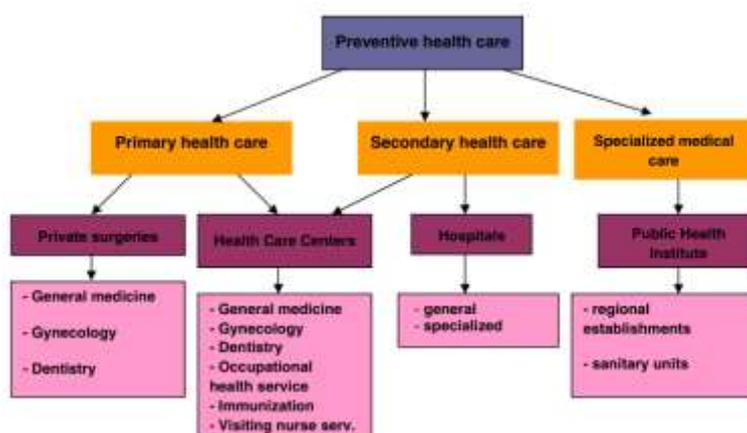
		<p>healthcare institutions in network</p> <p>8. prior consent to public health institutions allowing them to conclude mutual agreement for performing healthcare services</p> <p>9. licensing health care institution in network for healthcare services/work</p> <p>10. granting public authority to chambers for certain tasks</p> <p>11. appointing authorized representatives and their deputies for post-mortem examination</p>
6	Law on human organ transplantation	<p>1. license for organ transplantation in health care institutions in network</p> <p>2. license for tissue transplantation and tissue bank, including musculoskeletal grafts, skin tissue, heart vessels and eye tissue in health care institutions</p> <p>3. licensing laboratories for immunogenic processing and tests for matching the tissues of the recipient and the donor</p> <p>4. import and export permit for tissue banks</p>
7	Law on public health	<p>1. licensing public health institutions for active and passive immunization and chemoprophylaxis for travelling passengers</p> <p>2. working permit to individual or legal entity for treatments within traditional or complementary medicine – skin treatment (use of solariums, permanent hair removal and other activities, care and beautification) or skin penetration (tattooing, piercing, permanent make-up and acupuncture, botox usage, non-surgical liposuction and laser usage)</p>
8	Law on complementary and alternative medicine	<p>1. work permit for applying CAM therapies and practices</p> <p>2. granting public authority to chambers of CAM practitioners</p>
9	Law on medicines and medical aids	<p>1. permitting emergency imported medicines in public health institutes</p> <p>2. permitting import and usage of donated medicines</p> <p>3. permitting medicine prices</p>
10	Law on percussors	<p>1. permitting trade with percussors</p> <p>2. permitting import, export, transport and transit of percussors</p>
11	Law on chemicals	<p>1. registration license for trade with new substances/mixtures</p> <p>2. registration license for alternative usage of chemical name</p> <p>3. license for production of chemicals</p> <p>4. license for trade with chemicals</p> <p>5. registration license for trade with hazardous chemicals</p> <p>6. license for trade with biocide products</p>
12	Law on control of narcotics and psychotropic substances	<p>1. license for production of poppy</p> <p>2. license for cultivation of cannabis</p> <p>3. license for import, export and transit of substances and plants classified in II and III register lists, as well as their precursors</p>



4 LEGISLATION FRAMEWORK AND ORGANISATION OF GOVERNMENT LEVELS WITH THEIR RESPONSIBILITIES IN HEALTHCARE

- 4.1 The North Macedonian health service is comprised out of 3 levels: primary, secondary, and tertiary. The health institutions are usually private or public type, as referred in Figure 1: Health institutions authorized in preventive healthcare¹.

Figure 1: Health institutions authorized in preventive healthcare



Source: Kamcev, N., Angelovska, B., Kamceva, G., & Richter, K. (2010). Health Organization in Republic of Macedonia—the place of preventive health care in the medical health system: advantages and disadvantages. *EPMA Journal*, 1(4), 595-599.

- 4.2 According to the Public Health institute the specialized care is carried through the National Health Care Centre in Skopje, regional health care centres and hygiene-epidemiological sanitary units. The health system and implementation of health care is financed through Health Insurance Fund (hereinafter “HIF” or “Fund”) and income generation of the in 2020 in 35,842,102 TMKD is comprised out of contributions from salaries for social funds 85.42% (30,615,518 TMKD), non-tax revenues 1.47% (527,506 TMKD) and transfers from other levels of government 13.11% (4,699,078 TMKD)².
- 4.3 The distribution of the concluded agreements for primary health care general in year 2019, the Fund saw the need to increase the contract fees, so they increased by 15% of all private health care institutions that provide specialist-consulting health services, a trend that continued in 2020. The total value of the agreed fees in 2020 for PHIs that perform specialist

¹ Kamcev, N., Angelovska, B., Kamceva, G., & Richter, K. (2010). Health Organization in Republic of Macedonia—the place of preventive health care in the medical health system: advantages and disadvantages. *EPMA Journal*, 1(4), 595-599.

² <http://www.fzo.org.mk/WBStorage/Files/Godisen%20izvestaj%202020.pdf>



- consultative health care - medical activities is 235.8 million MKD. Compared to 2019 year the number of contracts is the same while the value has increased as a result of the increase of contractual fees for PHIs in 2020³.

- 4.4 Assembly of the Republic of Macedonia, the Government and the Ministry of Health are main authority bodies that propose and adopt changes to the legal framework in order to keep the healthcare system fair and accessible to everyone. The main legislative framework consists out of the Law on Health protection as concerning Healthcare for population, followed by the Law on Health Insurance and Law on Medicines and Medical Devices, as well as all acts and by laws for public health, health access and preventive care. The legislation is in line with healthcare recommendation of the WHO and EU institutions. Nevertheless, the effort could be bigger as there are a lot of alterations and the overlap of the authorities⁴.
- 4.5 The Law on Healthcare⁵ (hereinafter "LoH") is controlling the system and organization of health protection and the performance of healthcare activity. Moreover, it guarantees rights and the established and interests of the country in the provision of health protection, the healthcare institutions, the employment, rights and duties, responsibility, assessment, termination of employment, protection and decision-making upon the rights and obligations of healthcare workers and healthcare co-workers, the quality and safety of healthcare activity, the chambers and professional associations, the marketing and advertising of healthcare activity, the performance of healthcare activity in case of emergencies, and the supervision of the performance of healthcare activity.
- 4.6 At most importance is the right to health protection and the provision that no one must endanger the others. The healthcare activity, in terms of LoH, includes all measures and implementation of measures and activities for protection, promotion and improvement of the public health as well as individual healthcare. The main public authority that is performing activities, as well as supervision and registrations (Central Register of the Republic of North Macedonia) of activities is the Ministry of Health (Hereinafter "MoH").
- 4.7 The LoH is determining 3 healthcare activities levels: the detection and treatment of diseases and injuries at doctor's offices and polyclinics, dental laboratories, health centres and pharmacies, is part of the primary level; the secondary level includes, based on the severity of the illness, the need of expert specialized diagnostics and treatment, professional and technological complexity and multidisciplinary approach, that is, the necessity of hospital

³ <http://www.fzo.org.mk/WBStorage/Files/Godisen%20izvestaj%202020.pdf>

⁴ Kamcev, N., Angelovska, B., Kamceva, G., & Richter, K. (2010). Health Organization in Republic of Macedonia—the place of preventive health care in the medical health system: advantages and disadvantages. EPMA Journal, 1(4), 595-599.

⁵ Official Gazette of the Republic of Macedonia" nos. 43/2012, 145/2012, 87/2013, 164/2013, 39/2014, 43/2014, 132/2014, 188/2014, 10/2015, 61/2015, 154/2015, 192/2015, 17/2016, 37/2016 and 20/2019 and "Official Gazette of the Republic of North Macedonia" no. 101/2019



health treatment cannot be provided at primary level. And third level contains provision of health services that require professional, organizational and technologically complex and multidisciplinary healthcare treatment, according to Articles 30-39 of the LoH.

PROCEDURE AND PROVISIONS OF HEALTHCARE

Healthcare institution licencing

- 4.8 The healthcare institution can be established for performance of healthcare services, but then again, they need consent by the Ministry of Health (regulated by section IX. Licenses for carrying out a healthcare activity in the network of healthcare institutions of LoH). Therefore, any healthcare activity at primary, secondary or tertiary level is possible only on the basis of a license. Licence is granted for period of 35 years. Importantly, the licence is granted to a natural person and the person shall be obliged to establish a private healthcare institution in the time period determined by the decision on granting the license.

The licence granting procedure is conducted by MoH. The license granting procedure for each new separate license starts at least 3 months before the expiry of the period for which the existing license has been granted. The commencement of the license granting procedure particularly contains⁶:

- “...- an explanation of the justification to grant a license,
- a statement of its aims,
- a subject-matter of the license and basic requirements for license granting,
- a type of license granting procedure,
- a calculation of the amount and the manner of payment of the license fee,
- a manner and deadline for conducting the license granting procedure, and
- an amount of the fee for issuing the tender documentation.”*

- 4.9 An “open call” procedure for the license granting is prepared, organized and implemented by the commission for implementation of license. The commission members are persons among the employees in the Ministry of Health and experts in the appropriate field for which the license is being granted. The responsibilities of the commissions are: the preparation of tender documentation; announcement of the public call; organization of the acceptance of applications and bids; provision of explanations and submission of additional information and documents; review and assessment of the bids and ranking the candidates proposing the first-ranked to be selected as a license holder; submission of a proposal for termination of the procedure, and performance of other activities necessary for implementation of the procedure.

⁶ As referred in paragraph 4 of the Article 229 of LoH.



- 4.10 The exclusion criteria includes the persons that: are married, related up to the second degree or related by adoption or guardianship to the bidder or the candidate, his/her legal representative, and in the cases where the bidder or the candidate is a legal entity, to the members of its governing, supervisory or other bodies and management bodies as well; during the last three years, have been employed or have been members of the governing bodies of the candidate; or are in other legal or factual relationship with the candidate. The commission adopts decision in plenary sessions and with majority of votes of the members.
- 4.11 The commission may entrust the preparation of the tender documentation to a scientific or professional organization or to experts in the appropriate field. The minimum number of eligible bidders is at least 1. The tender documentation particularly contains: an invitation to submit a bid, including instructions; requirements it must meet, including also the technical specifications; criteria for assessment of the bids; instructions for the bidders how to prepare the bid; a period for which the license is granted; a draft text of the license agreement; and other requirements depending on the subject-matter of the license. A copy and draft of licence agreement between MoH and Licence holder should be enclosed.
- 4.12 According to Paragraph 19 of the Article 229 of the LoH the license agreement concluded with the healthcare institution being granted the license shall mandatorily contain provisions on:

*“...- the type of healthcare activity to be performed on the basis of the license,
 - the commencement of the license use,
 - the license granting for a period of up to 35 years,
 - the license fee,
 - the premises and equipment for performance of the healthcare activity,
 - the data on the people with whom the license holder shall work in a team, and
 - provisions on the obligation of the license holder to require previous consent from the Ministry of Health for each change pertaining to the contents of the license agreement, and especially change of the person who is on the team of the license holder and change of the premises where the license holder performs the activity.”*

The 6th line is the only one not mandatory.

- 4.13 The commission shall be obliged to make possible for the interested candidates to take tender documentation immediately after the date of announcement of the public call. However, the MoH may charge the bidders and the candidates a fee for issuing the tender documentation, on the basis of the actual costs incurred for the activities necessary for its preparation. The tender documentation may be amended 6 days prior to the expiry of the deadline for submission of bids or applications for participation at the latest.
- 4.14 The public call according to Article 230 of LoH shall particularly contain:

“...- an explanation of the justification for granting a license,



- a statement of its aims,
- a subject-matter of the license and basic requirements for license granting,
- a type of license granting procedure,
- a calculation of the amount and the manner of payment of the license fee,
- a manner and deadline for implementation of the license granting procedure, and
- an amount of the fee for issuing the tender documentation.”

- 4.15 The deadlines start running as of the day the call is sent for announcement. The deadlines for submission of bids and the application for participation shall be accordingly published and determined depending on the complexity of the license granting procedure and the time reasonably required to prepare the bid. However, the deadlines may be extended by the MoH at any time prior to the expiry of the deadline, given that the bidders and the candidates are informed in a timely manner. Furthermore, the deadlines shall be extended if the tender documentation has not been submitted on time to all the bidders or candidates, if there has been an amendment to the public call and/or the tender documentation, as well as in other cases where the Ministry of Health establishes justification for extension of the deadlines for objective reasons. Unless otherwise regulated by this Law, the submission of bids and applications for participation in the case of an open call, cannot be shorter than 26 days as of the day of sending the call for announcement. The bid and the application for participation shall be submitted in a manner and form determined by the public call. The persons who have taken the tender documentation have the right to submit bids and an application for participation.
- 4.16 The participation in the process for submission of bids may be conditioned by providing a guarantee by the bidder in a form of deposited funds or a bank guarantee that cannot be lower than 3% of the assessed value of the license. If the bidder provides the guarantee in the form of deposited funds, they shall be paid to an appropriate account within the treasury account.
- 4.17 The guarantee shall be kept for the benefit of the Ministry of Health in case the bidder withdraws the bid after the deadline for submission of bids, the first, the second-ranked bidder refuses to conclude the license agreement, and the most favourable bidder does not meet particular requirements for return of the guarantee for participation in the procedure, anticipated by the tender documentation.
- 4.18 Following the expiration of the deadline for submission of bids, the commission publicly opens bids in the presence of authorized representatives of the bidders in a place and at a time determined by the public call. The public opening of the bids is conducted in a manner determined by the public call. The commission establishes a list of candidates on the basis of



their personal standing, their ability to perform professional activity, their economic and financial situation, as well as their technical and professional ability. The evaluation of the bids will be only of those bidders selected as favourable. The report is published upon the completion of the valuation and notification of all the bidders about the results of the selection procedure. The MoH may require the bidders and the candidates to prove their membership or inclusion in a professional association or organization entered in an appropriate register or to submit a special statement or reference in order to prove their right and ability for performance of a professional activity as well as their technical and professional ability to execute the subject-matter of the license.

- 4.19 Criterion on the basis of which the MoH bases its selection of the best bid is financially or economically most favourable (evaluated on the basis of the criteria related to the performance and functional requirements that include quality, price of works and services, current costs, economic profitability compared to the costs). The methodology for expressing the criteria in points is adopted by the Minister of health. The commission prepares a written report on the evaluation for each license granting procedure. The report on the evaluation and the proposal of the decision on selection of the most favourable bid is signed by the president and the members of the commission and it is submitted to the Minister of health.

According to the Paragraph 5 of the Article 231 of the LoH the decision on selection of the most favourable bid is final and an administrative dispute may be initiated against it. The decision is submitted to all bidders or candidates within a period not longer than 15 days as of the day of its adoption.

According to Article 63 of the LoH:

“(2) The license for work of the healthcare institution shall contain the following data:

- name and head office of the healthcare institution,*
- name and surname, that is, name of the founder, personal identification number and address, that is, head office,*
- type of the healthcare institution,*
- responsible holder of the healthcare activity and the other healthcare workers (personal name and surname, title, address of the permanent or temporary place of residence),*
- type and manner of performance of the healthcare activity in the network or type and manner of performance of the healthcare activity outside the network, and*
- list of health services that, in accordance with the requirements that are fulfilled, may be provided by the healthcare institution...”*

- 4.20 In case of relocation of the Licence the MoH adopts a decision on revocation of the license for work of the healthcare institutions if: within the determined time period, which cannot be



shorter than 45 or longer than 60 days depending on the time necessary to eliminate the irregularities, it does not remove the irregularities; it does not notify the Ministry of Health of the changes in the data that are entered in the register of healthcare institutions within a period of 15 days after their occurrence; on the basis of a legally valid decision, nullity of the entry of the healthcare institution in the Central Register of the Republic of Macedonia is established; a sanction prohibiting the performance of the activity has been imposed due to failure to meet the requirements for performance of the activity; it carries out an activity contrary to the license for work, and; it does not implement the provisions of this Law and the acts adopted on the basis of this Law.

4.21 Termination of the license as regulated in Article 232 of the LoH, happens upon:

- “... - expiry of the validity period of the license agreement,*
- unilateral cancellation of the license agreement by the Ministry of Health,
- unilateral cancellation of the license agreement by the license holder,
- agreed cancellation of the agreement,
- bankruptcy or liquidation of the license holder, and - other cases envisaged by law and the license agreement.”

Furthermore the unilateral cancellation of the license may be pronounced when: the activity transferred by the license is performed in an inappropriate or low quality manner, considering the rules, parameters and other conditions whereby appropriate performance of the activity established by the license agreement is determined; the license holder has significantly violated the provisions of the license agreement or the laws and regulations applicable to the license agreement in another manner; the license holder has terminated or caused termination of the provision of the public service; the license holder has lost the economic, technical or operative abilities required for performance of the activity under a special law and the license agreement; and the license holder has not acted upon the imposed measures in the supervision and control procedure conducted in accordance with a special law.



The governance of the healthcare institutions

4.22 The public healthcare institution is governed by a governing board⁷:

“...(3) The governing board of the public healthcare institutions of primary health protection shall be composed of 5 members, 3 of whom shall be representatives of the founder and 2 representatives of the local self-government units, 1 of whom shall be appointed by the council of the municipality on the territory of which the head office of the public healthcare institution is located, and the other by the council of the municipality with the largest number of citizens on the territory covered by the healthcare institution, excluding the municipality on the territory of which the head office of the healthcare institution is located in case it has the largest number of citizens...” and as exemption for City of Skopje: the two representatives of the local self-government units in the public healthcare institution providing primary health protection on the territory of the City of Skopje shall be appointed by the Council of the City of Skopje..”

4.23 The members the above-mentioned governing body can be anyone who holds at least a university degree and has at least 5 years of work experience in the field of health, economy or law. However, the law prohibits from being in governing body for: employed or holds stocks or shares in legal entities that manufacture, or trade in, medications, medical devices, that is, medical equipment, a close person to a member of the governing board, and in other cases determined by the regulations in the field of prevention of conflict of interests.

4.24 Dismissal and termination are on: 1) the basis on which he/she has been appointed is no longer valid; 2) he/she has not attended the sessions of the governing board without justification at least twice a year; 3) if it is additionally confirmed that he/she is a person close to a member of the governing board, as well as in other cases determined by the regulations in the field of prevention of conflict of interests; 4) it is additionally confirmed that he/she has personal, through a third party, or on any other basis, interests that may in whatever manner affect his/her independence and impartiality; 5) he/she meets the obligations in the governing board in a negligent or inefficient manner; and 6) he/she works contrary to the provisions of this LoH.

4.25 The management body (director) of Healthcare institutions the person has to follow requirements⁸:

“...1) to be a citizen of the Republic of Macedonia; 2) at the moment of appointment, not to be issued an effective injunction banning him/her from exercising a profession, business or office; 3) to have completed a higher education in the field of medical or dental or pharmacy sciences, a higher education - a graduated speech therapist, a higher education - specialist

⁷ According to Article 100 of the LoH.

⁸ As determined in Article 104 of the LoH.



in medical biochemistry, a higher education in the field of economy or law or public health management, or completed academic studies with at least 240 ECTS, that is, at least VI B level under the National Framework for Higher Education Qualifications; 4) to have at least five years of work experience in a healthcare institution, that is, in the economy, finances, law or management or in the system and organization of the health protection and health insurance and a passed director examination; 5) to offer a work program for the public healthcare institution of the highest quality; and 6) to hold one of the following internationally recognized certificates for active knowledge of English Language which is not older than five years: - TOEFL IBT - at least 74 points, - IELTS - at least 6 points, - ILEC (Cambridge English: Legal) - at least B2 level, - FCE (Cambridge English: First) – passed - BULATS - at least 60 points, or - APTIS - at least B2 level...”

- 4.26 Some exceptions are for the experts is needed by transfer of skills and knowledge in the field of medicine and management of healthcare institutions and who has to be: 1) to be a citizen of an OECD member state, 2) at the moment of appointment, not to be issued a penalty or misdemeanour sanction banning him/her from exercising a profession, business or office by an effective court ruling in the country of citizenship, in another OECD member state, or in the Republic of Macedonia; 3) to have completed the first, second and/or third cycle of studies abroad in the field of medical or dental sciences, that is, pharmacy or a higher education abroad in the field of economic or legal sciences, public healthcare management or completed academic studies abroad, and 4) to have at least five years of work experience in a healthcare institution in an OECD member state at managerial position, may be appointed a director. The director has to follow orders, instructions and plans of MoH.
- 4.27 There is also possibility that duty of director is performed by two people, if the medical centre has more than 1000 employees, in that needs to be⁹:

“...1) to be a citizen of the Republic of Macedonia; 2) at the moment of appointment, not to be issued an effective injunction banning him/her from exercising a profession, business or office; 3) to have completed a higher education in the field of medical and dental sciences, a higher education - a graduated speech therapist, a higher education - specialist in medical biochemistry, or completed academic studies with at least 240 ECTS, that is, at least VI B level under the National Framework for Higher Education Qualifications; 4) to have at least five years of work experience in a healthcare institution and a passed director examination in accordance with this Law; 5) to hold one of the following internationally recognized certificates for active knowledge of English Language which is not older than five years: - TOEFL IBT - at least 74 points, - IELTS - at least 6 points, - ILEC (Cambridge English: Legal) - at least B2 level, - FCE (Cambridge English: First) - passed - BULATS - at least 60 points, and - APTIS - at least B2 level...”

⁹ As determined in Article 105 of the LoH.



4.28 The exceptions are the same as with only one director. The appointment and dismissal as determined in the Article 107 of the LoH:

“...(1) A director of a public healthcare institution shall be appointed on the basis of a public announcement opened by the governing board of the public healthcare institution. (2) The director of the public healthcare institution shall be appointed, that is, dismissed by the minister of health. (3) The minister of health may request an opinion from the Health Council regarding the appointment, that is, the dismissal of the director of the public healthcare institution. (4) The term of office of the director shall last four years.”

4.29 According to article 105 of the LoH the responsibility of director is:

“...(8) The medical and the organizational director shall have joint competence and responsibility for everything that is not in the exclusive competence of the medical or the organizational director, and in particular for:

- preparation of a draft plan for public procurement and its submission to the governing board of the public healthcare institution for adoption, as well as planning, decision-making,*
- signing public procurement contracts, monitoring and implementation of the public procurement for the needs of the public healthcare institution,*
- employment in the public healthcare institution,*
- termination of employment of healthcare workers,*
- roster of shifts of healthcare workers and healthcare co-workers and formation of working groups, and*
- adoption of decisions on rewarding all the employees in the public healthcare institutions...”*

4.30 Before procuring the equipment, the director needs to conduct a procedure for public procurement. If the director fails to conduct a procedure for public procurement of medications, consumables and medical devices, the Minister of health instructs the director to initiate a procedure for public procurement within a period of 15 days. This time period can be extended for another 15 days. If the director does not conduct public procurement the Minister of health dismisses the director and appoints an acting director until the appointment of a director at an open announcement, but for a period not longer than 6 months.

4.31 The director can be dismissed due to¹⁰:

“...1) at his/her personal request; 2) in the case of appearance of any of the reasons due to which, according to the regulations in the field of employment, his/her employment terminates in accordance with law; 3) if he/she works or acts contrary to this and another law, the statute and the acts of the institution, or without any justification he/she does not implement the decisions of the governing board or acts

¹⁰ According to Article 111 of the LoH.



contrary thereto; 4) if his/her negligent and incorrect work causes damage to the institution or if, due to negligence or non-fulfilment of the obligations, the performance of the activity of the institution is disturbed; 5) if the institution ends two consecutive six-month periods with losses in its financial operation; 6) if the program referred to in Article 148 paragraph (2) of this Law is not adopted and/or he/she does not ensure its implementation, that is, he/she does not provide funds in the amount necessary for the implementation of the specialty, that is, sub-specialty training out of the funds of the healthcare institution; 7) if he/she does not implement the recommendations of the professional supervision conducted; 8) in the case of greater employment than the one planned with the work program of the public healthcare institution; 9) due to pay-outs for overtime work higher than the ones actually done and for contractual obligations other than those planned; 10) if he/she obstructs the exercise of the rights and obligations of the beneficiaries of health protection; 11) if he/she does not submit a regular six-month report on the work; 12) if a complaint pursuant to Article 193-a of this Law has been filed to the director of the healthcare institution for two consecutive or three times in the course of a year, but he/she 92/316 fails to establish a commission for conducting the disciplinary procedure for the disciplinary offense, nor adopts a decision imposing a disciplinary measure, 13) if the data required for measuring the key success indicators are not entered for two consecutive or three times in the course of a year in the integrated health information system in accordance with the regulations in the field of health records within the time period and in the manner pursuant to Article 239-b paragraph (2) of this Law or if incorrect or unauthentic data required for measuring the key success indicators are entered, and 14) if he/she fails to pay the contractual penalty referred to in Article 239-c paragraph (4) of this Law twice the amount pursuant to Article 239-c paragraphs (7), (8), or (9) of this Law, within the additional time period set out in Article 239-c paragraph (4) of this Law..”

- 4.32 Licence for Competence of the chambers is issued in accordance with Article 123 of LoH and is issued for 4 years. The licence can be obtained if the professional examination is passed and the person has a validated diploma for completed corresponding education, and a proof of recognized probationary work and a passed professional examination. A healthcare worker with a university degree who has obtained a license for work abroad may obtain a license for work if they possess a recommendation from the chamber where he/she has been a member, and a proof for previous work experience in the field in which he/she requests a license for work.
- 4.33 Renewal of the licence is done if during the validity period of the license, the person has acquired an appropriate number of scores through continuous professional development, staying current with the innovations in the medicine, dental medicine, pharmacy, and has upgraded the personal knowledge, and if he/she has spent at least 60% of the validity period of the license for work (the work in the office is not included) in the field for which a license for work has been obtained. If the person does not have all trainings and certifications there is possibility of temporary extension for 6 months.



- 4.34 The licence for carrying out a healthcare activity in the network of health institution, according to section IX. Of the LoH. Timeline for issuing is period of 35 years.
- 4.35 Expert commissions may be formed within the Ministry of Health as expert and advisory bodies of the Minister of health regarding particular types of healthcare activity. The tasks of the expert commission include preparation of professional instructions for evidence-based medicine, preparation of expert views and analysis, and review of reports in the field of quality of health protection and safety in the performance of the healthcare activity.
- 4.36 The supervisions is done by the Ministry of Health on the lawfulness of the work of healthcare institutions, according to article 295 of LoH.

HEALTH CARE VULNERABILITIES AND RECOMMENDATIONS

In this part of the report, we first present general vulnerabilities and recommendations regarding healthcare in Northern Macedonia. Then we present in more detail de jure vulnerabilities (the vulnerabilities for abuse of discretionary powers as defined by the regulation itself) and de facto vulnerabilities (the vulnerabilities for abuse of discretionary powers when it comes to implementation of the procedure). We also offer recommendations.

In the body of the report, we only mention and list high vulnerabilities, however in Annex to this report we include full table of Articles screened for risks for abuse of discretionary powers in the regulation itself and in the implementation of the procedure.

General vulnerabilities in healthcare and recommendations

- 4.37 In December 2020 the Republic of North Macedonia released National strategy for preventing corruption and the conflict of interests 2021-2025. Among 14 critical sectors was also Health care sector. Primarily the problem is that The MoH does not *assess the risks of corruption*, nor does it mention in one of the strategic documents. Secondly the risks of corruption in healthcare are mainly connected to the performance of the basic activity - provision of health services, employment and *especially in public procedures procurement*, having in mind that in this sector a large number of procurements are continuously performed with high value (of medical equipment, drugs and other necessary goods / services) in order to allow operational and uninterrupted performance of daily activities. Furthermore the most exposed is the fact that: "...(1) There are no effective criteria for determining contractual fees (limits / budgets) for health institutions (PHI and PHI) and for the prices of health services and drugs, nor criteria for transparent budgeting and allocation intended for PA, new technologies and drugs,



methods for health services; (2) Subjectivism in the choice of drugs that are covered by public funds, i.e. from the health insurance contributions of the citizens, and the regulation for evidence-based medicine is not applied consistently; (3) Abuses in the procedures for giving / receiving donations, clinical studies and projects; (4) Unethical practices in marketing drugs; (5) Transparent and objective decision-making in the procedure for treatment abroad...”

- 4.38 The fundamental vulnerability is unequal geographical distribution of health services, profit orientation and commercialisation of the practice, overwhelming paperwork, as these factors act as enablers for permit and licence issuing¹¹. The Medical Chamber of the Republic of Macedonia has also listed article that addresses problems in hospital health care, as main one they list: “...Discrepancy between the funds provided and the requirements for fulfilling sophisticated services. The health package in most hospitals, and especially in university clinics, is significantly "more expensive" than the budget received by that public health institution. In such a state of real impossibility to provide timely and quality health service, the culprits are the health workers¹² ...”. Moreover, there is also inefficient use of facilities; old equipment and apparatuses; lack of certain healthcare services, and lack of transparency in the management of human resources that can lead to vulnerability in healthcare.
- 4.39 There is little corruption in public health recognised and reported in various corruption reports, but citizens through various surveys stated the presence of the high level of corruption in healthcare. One reason public procurement in healthcare is also inclusion of it into National Strategy for Prevention of Corruption and Conflict of Interest and the Action Plan for Implementation 2021 – 2025¹³ as one of the 14 problematic areas. Essential in this sector is the establishment of transparent and appropriate criteria for the use of public finances, together with digitalization and connection in financial-accounting management of health care providers. In addition, it is necessary to adjust the system of price formation and public procurement for medicines in accordance with the practices and regulations.
- 4.40 Furthermore, the National strategy²¹ found out that due to the lack of an integrated data system for the costs of public procurement, there is a large danger of subjectivity in determining the input costs involved information of the reference price of the health services. The main challenge to tackle corruption starts as primarily includes the Ministry for health and the independent bodies within it, the Health Insurance Fund (HIF), as well as operating units: clinical centres, polyclinics and other institutions that perform activity in the field of public health.

¹¹ <https://www.fomoso.org/en/mosopedia/background-knowledge/challenges-in-the-healthcare-system-of-the-republic-of-macedonia/>

¹² <http://www.lkm.org.mk/mk/zapis.asp?id=215>

¹³ National Strategy for Prevention of Corruption and Conflict of Interest and the Action Plan for Implementation 2021 – 2025



- 4.41 Main risks of corruption in healthcare are mainly related: "...to the performance of the basic activity- provision of health services, employment and especially in public procedures procurement, having in mind that in this sector a large number of procurements are continuously performed with high value (of medical equipment, drugs and other necessary goods / services) to enable operational and uninterrupted performance of daily activities¹⁴ ...". Not long ago, there has been example of top official wanted to pursue untransparent and shady deal with big pharmaceutical firm, without any public interest behind it¹⁵.

De jure and de facto vulnerabilities and recommendation

We have been able to identify several instances of risk exposure in the screening for discretionary powers in the procedures for granting a license to perform activity in the network of health institutions in Northern Macedonia, however, most of them present only a small to moderate risk in the healthcare sector.

We have observed that currently the prices for performing the healthcare services on foreigners are not universal and can differ between various health institutions and physicians. The current body of law gives the Minister of Health discretionary power to give consent to directors of PHI's for the variations in the price list of healthcare services for foreigners. This represents a small corruption risk therefore it is proposed that the Minister of Health to adopt a price list that will be uniform for all public health institutions.

Moreover, on the topic of decisions for establishment and decisions for license for work of a health institution, we have found out that some parts of the Law have not yet been adopted in practice. Discretionary powers are not explicitly provided by the norm, but due to the absence of a adopted regulation in practice, numbers of "abuses" occur, e.g. the issues related to spatial planning are solved or decided by making a geodetic report.

In addition, moderate risk for the abuse of discretionary power has been found in the licensing procedures for health institutions. The risk stems from the fact that no appointment procedure has been provided for the election of members into the commission responsible for granting licenses to health institutions. Hence, the possibility for "favouring" individual employees is open, but it must be determined whether it is a risk to the legality of the procedure through which the commission works to determine harmfulness.

¹⁴ National Strategy for Prevention of Corruption and Conflict of Interest and the Action Plan for Implementation 2021 – 2025

¹⁵ <https://balkaninsight.com/2021/03/12/north-macedonia-to-probe-corruption-concerns-in-vaccine-procurement-affair/>



Article No.	Service Procedure /	Regulation that regulates it	Further regulated by a bylaw	Exposure to risk of corruption / conflict of interest	Are there normative barriers to digitalization	Discretionary powers	The scope of discretionary powers
1	Conditions for performing health activity of patients who pay for health services with personal funds	ZZZ art.44	Article 44-a paragraph 3, the price list for costs for health treatment of foreigners is adopted by the Director of the PHI, with the consent of the Minister. It is proposed that the Minister of Health for health institutions to adopt a price list that will be uniform for all public health institutions.	small	no	there is	The MoH can give permission to different PHIs, which in different ways will provide a cost list for the same service.
2	Decision for establishment and decision for license for work of a health institution	ZZZ. Articles 62, 63, 64 (supplementary provisions Articles 57-67)	Article 60 paragraph 5 The Minister prescribes the necessary space, equipment and professional staff for establishment, starting work and performing health activity in the PA (Act has not been adopted). Article 62 paragraph 1, 7, Application form is prescribed by Minister of Health, in accordance with MISA (TO RECEIVE THE FORMS and the Act has not been adopted).	small	no	no	Discretionary powers are not explicitly provided by the norm, but due to the absence of a adopted regulation in practice, numbers of "abuses" occur, e.g. The issues related to spatial planning are solved or decided by making a geodetic report. Hence, the question of the existence of quality standards is left open, especially since the content of the report for establishment from Article 61, paragraph 1, although it must be prescribed by the act provided in Article 60, paragraph 5, does not currently exist.



6	Licensing (PROCEDURE)	ZZZ. Art.229	<p>Is there / can be adopted: Guidelines for the manner of work of the Commission for conducting the procedure for granting a license to a health institution in the network</p> <p>Rules of Procedure of the Commission - who would carry it?</p> <p>it is proposed that these questions be answered with the "Rulebook on the criteria for selection of members of the Commission for conducting a procedure for granting a license to perform health activity in the network of health institutions" and with "Guidelines for the manner of work and action of the Commission for conducting a procedure for granting a license for performing health activity in the network of health institutions.</p>	<p>small / moderate. The orders from which the members of the commission can be elected are determined. The law does not provide criteria outside the affiliation of the order (eg employee of the MoH). The possibility for "favoring" individual employees is open, but it must be determined whether it is a risk to the legality of the procedure through which the commission works to determine harmfulness.</p>	<p>Article 229, paragraph 17, to replace the word "copy" with "copy"</p>	<p>Art. 229 para. 7, 8, 9, para. 12 al.7. Establishment of a Commission for conducting a procedure for granting a license, established by the MoH</p>	<p>The law provided: organization, members, from which ranks the members can be elected. An appointment procedure (appointment without a procedure) is NOT prescribed. Paragraph 10 provides for a conflict of interest-grounds for incompatibility of a member.</p>
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ANNEXES

Annex 1

Screening and mapping
The Law on Healthcare Protection

Article No.	Service / Procedure	Regulation that regulates it	Further regulated by a bylaw	Exposure to risk of corruption / conflict of interest	there are normative barriers to digitalization	discretionary powers	scope of discretionary powers
1	Conditions for performing health activity of patients who pay for health services with personal funds	ZZZ art.44	Article 44-a paragraph 3, the price list for costs for health treatment of foreigners is adopted by the Director of the PHI, with the consent of the Minister. It is proposed that the Minister of Health for health institutions to adopt a price list that will be uniform for all public health institutions.	small	no	there is	The MoH can give permission to different PHIs, which in different ways will provide a cost list for the same service.



2	Decision for establishment and decision for license for work of a health institution	ZZZ. Articles 62, 63, 64 (supplementary provisions Articles 57-67)	Article 60 paragraph 5 The Minister prescribes the necessary space, equipment and professional staff for establishment, starting work and performing health activity in the PA (Act has not been adopted). Article 62 paragraph 1, 7, Application form is prescribed by Minister of Health, in accordance with MISA (TO RECEIVE THE FORMS and the Act has not been adopted).	small	no	no	Discretionary powers are not explicitly provided by the norm, but due to the absence of a adopted regulation in practice, numbers of "abuses" occur, e.g. The issues related to spatial planning are solved or decided by making a geodetic report. Hence, the question of the existence of quality standards is left open, especially since the content of the report for establishment from Article 61, paragraph 1, although it must be prescribed by the act provided in Article 60, paragraph 5, does not currently exist.
3	Termination of work and revocation of the work permit of a health institution	ZZZ. 65	TO CHECK WITH MOH.	small	no	no	
4	Determining the license and licensees	ZZZ. Article 227 paragraphs 1, 3, 4, 5					



5	Regulations that apply and documentation after the announcement for granting a license	ZZZ. Art.228		small	no	no	
6	Licensing (PROCEDURE)	ZZZ. Art.229	<p>Is there / can be adopted: Guidelines for the manner of work of the Commission for conducting the procedure for granting a license to a health institution in the network</p> <p>Rules of Procedure of the Commission - who would carry it?</p> <p>it is proposed that these questions be answered with the "Rulebook on the criteria for selection of members of the Commission for conducting a procedure for granting a license to perform health activity in the network of health institutions" and with "Guidelines for the manner of work and action of the Commission for conducting a procedure for granting a license for performing health activity in the network of health institutions.</p>	<p>small / moderate. The orders from which the members of the commission can be elected are determined. The law does not provide criteria outside the affiliation of the order (eg employee of the MoH). The possibility for "favoring" individual employees is open, but it must be determined whether it is a risk to the legality of the procedure through which the commission works to determine harmfulness.</p>	<p>Article 229, paragraph 17, to replace the word "copy" with "copy"</p>	<p>Art. 229 para. 7, 8, 9, para. 12 al.7. Establishment of a Commission for conducting a procedure for granting a license, established by the MoH</p>	<p>The law provided: organization, members, from which ranks the members can be elected. An appointment procedure (appointment without a procedure) is NOT prescribed. Paragraph 10 provides for a conflict of interest-grounds for incompatibility of a member.</p>



					Article 230, paragraph 12, paragraph 19 and paragraph 20. The circumstances under which the public opening is organized, if it must be with physical presence, constitute an obstacle for electronic opening. It is recommended to take the good practice of public openings through the electronic procurement system.		
7	Licensing (PROCEDURE)	ZZZ. Art.230	To adopt: Rulebook on the manner and form of submission of the bid and form of request for participation in the procedure for granting a license for / for paragraph 12, paragraph 19 and paragraph 20 for paragraph 3 must It is stipulated that the bidders and the candidates bear the cost for duplication of a copy of the tender documentation. p.31 A methodology already exists prescribed by the Minister			Art.230, para. 4, p.8, p. 13, paragraph 15 paragraph 27, paragraph 28, fee for obtaining tender documentation, amendments to the tender documentation, extension of deadlines, conditioning of bidders with a guarantee, free evaluation of the bidders to be members of chambers of commerce, evidence for ability.	
8	Licensing (PROCEDURE)	ZZZ.Ch.231, st.3,4,5			no	no	
9	Leasing part of the space to the PHI under Lease	ZZZ. Art. 231-a	Specifications are regulated by Announcement.		no	paragraph 2 formation of a commission	Writes only from the ranks of employees, there are no criteria for the status of employees.



10	Procedure for public bidding when renting part of the space of the PHI	ZZZ. Art. 231-b			paragraph 4 requires personal signature of the present representatives of the bidders in a record sheet. It is suggested that the words after the word "bidders" in paragraph 4 be deleted until the end of the paragraph	no	
11	Conditions for holding a public bidding and minutes of the public bidding	ZZZ. Art. 231-c			no	no	
12	Licensing	ZZZ. Art. 231			no	no	



					Article 231-e does not exist. Article 231j-paragraph 1 explicitly provides in writing. Note: The Law on Obligations does not contain an obstacle. The term "written form" means a document concluded in written form. Every document - whether electronic or printed is written because it is made in written form.		
13	Acting of the public body with the most favorable offer and acting that the first ranked did not conclude a lease agreement	ZZZ. Art. 231-d				no	
14	Deposit for participation in public bidding	ZZZ. Art. 231-f			no	no	
15	Right to object and appeal	ZZZ. Art. 231-e			no	no	



16	Lease contract	ZZZ. Art. 231-h		<p>there is Article 231-h, paragraph 1 and paragraph 3 In paragraph 1 to be added "and in electronic form". For item 3, the lease agreement is concluded in writing. After concluding the contract, the "tenant" submits it to a notary public for solemnization. The proposal is to replace the whole paragraph with: The signatures of the contracting parties are notarized.</p> <p>It must be noted that "solemnization" provides the lessor</p>	no	<p>* the eventual amendment of the Law will create an opportunity for alternative decision-making, which will be discretionary for the Commission but must exist - because electronic communication is the choice of the party</p>
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					with an enforcement clause in case of non-fulfillment of contractual obligations by the lessee. Hence, the authorized proposer of possible amendments to the IPH must take a position on this issue..		
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17	Termination of the license	ZZZ. Art.232			no	no	
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