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Qeveria - Vlada - Government
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Legal Analysis for simplification, merger or elimination of permits and licenses issued within the Ministry of Health, Ministry of Internal Affairs and Ministry of Environment, Spatial Planning and Infrastructure (infrastructure part)¹²³

December 2021

¹This legal analysis has been approved in the 50th Meeting of the Government of the Republic of Kosovo, with the decision No. 03/50 dated 23.12.2021.

² Kjo analizë juridike është miratuar në Mbledhjen e 50t-të të Qeverisë së Republikës së Kosovës me Vendimin Nr. 03/50 të datës 23.12.2021.

³ Ovo Pravna analiza ja odoberna na 50. Sednici Vlade Republike Kosovo sa brojem resenja 03/50, datum 23.12.2021.

Simplification of permits and licenses at the Ministry of Internal Affairs

In the process of simplifying permits and licenses at the Ministry of Internal Affairs and harmonizing them with Law No. 04/L-202 on Permit and License System, a total of 59 permits and licenses were analyzed, of which 36 procedures fall within the scope of the Department of Public Safety - Department of Weapons, Ammunition and Explosives, 19 procedures fall within the scope of the Department of Public Safety - Division of Private Security Services, and 4 procedures fall within the scope of the Department of Prevention.

During the analysis process, special focus was given to the legal basis of all relevant permits and licenses issued within the MIA, the procedure followed by the relevant departments, the documents required and the form of submitting them. Further, the flow of applications for relevant permits and licenses and the flow of permits issued by the MIA were also analyzed during the research. Moreover, the necessity of the existence of the permits and licenses, the function they perform as well as the possibility of simplifying them in terms of required documentation and payments were also considered during the analysis. At the same time, in the process of simplification, the possibility of merging some of them and removing them from the existing procedures within the Ministry was analyzed. During the analysis process, legal persons/businesses and companies exercising respective functions concerning which such permits and licenses are required were also consulted. During these meetings, the administrative burden that these procedures create for these businesses was discussed, as well as their necessity in the context of the risk associated with respective activities.

Of the 59 procedures analyzed, 28 of them have been proposed to be removed from the register, with 40 existing licenses remaining and 1 professional license added therein. Whereas, concerning all these 41 licenses, it is proposed to simplify the procedures by reducing the requirement for submitting documents issued by the MIA itself and lowering applicable fees.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry of Internal Affairs	DSP1	<p>1. Licence for manufacturing explosives and fireworks</p> <p>2. Licence for import, export, transit and transfer of explosives and fireworks</p> <p>3. Licence for use of explosives and fireworks</p>	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Paragraphs 1 and 2 of Article 29 of Law No. 04/L-022 on Civil Use of Explosives stipulate that the general license is issued for manufacturing, import/export/ transfer and use. These three licenses are issued parallel to the business registration procedure with the KBRA. Upon obtaining these licenses, companies are registered as entities for the manufacturing, import, export, transit, transfer and use of fireworks and explosives, but they are not granted the right to exercise the specified activity upon obtaining the general license.</p> <p>2. Paragraph 9 of Article 29 of Law No. 04/L-022 on Civil Use of Explosives specifies that licenses are valid for a period of 5 years, which implies that companies should be re-licensed after five years.</p> <p>3. The Minister's Decision No. 154/2016 on Setting of Fees specifies that the cost for obtaining each of these licenses is EUR 500. In other words, a company has to pay a fee of EUR 500 three times for each license, and they should be licensed every 5 years.</p>	<p>1. Amend in entirety Law No. 04/L-022 on Civil Use of Explosives, specifically paragraph 1 of Article 20 thereof, in order to abolish the obligation of legal persons to obtain a general license for the manufacturing, import, export, transit, transfer and use of fireworks and explosives, requiring instead of obtaining a license general registration at the Ministry of Infrastructure which would serve for all three activities (manufacturing, import/export/transfer and use).</p> <p>2. Amend Articles 31, 32, 33, 38 and 39 of Law No. 04/L-022 on Civil Use of Explosives in order to abolish the obligation to obtain a license by legal persons and to require their registration according to Article 7 of Law No. 04/L-202 on Permit and License System.</p> <p>3. Amend paragraph 9 of Article 29 of Law No. 04/L-022 on Civil Use of Explosives in order to determine the obligation of</p>	<p>1. Paragraph 1.41 of Article 2 of Law No. 04/L-022 on Civil Use of Explosives stipulates that the license is the authorization issued from the competent body of legal person, by which the holder is authorized to be engaged in a special type of business or other activity in compliance with terms prescribed in the license according to this law. This procedure is equivalent to the procedure required for business registration with KBRA. So, in addition to the application for business registration with KBRA, the legal person is obliged to be licensed (which is essentially a registration procedure) at the MIA. And with the licensing of the company, the legal person cannot start exercising its activity again since it requires special permits, so the practical relevance of licenses is the same as registering a business with KBRA. Therefore, for the sake of public safety and the state need to have knowledge about the existence of companies that exercise these activities, it is</p>

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					<p>4. Administrative Instruction No. 04/2013 on Criteria and Procedures for Licenses and Permits, and Administrative Instruction (MIA) No. 07/2013 – on UN Hazards Classification and Compatibility Groups foresee the licensing obligation in the same line as the Law.</p> <p>5. When applying for a license, the legal person is required to submit two documents which are issued by the MIA: (i) Certificates of authorized persons and (ii) Certificates of qualified persons. Also, when applying for a license for import, export, transit and transfer of explosives and fireworks, two additional documents are required which are also issued by the MIA, such as: (i) Driving certificate (special driving license for the transport of dangerous goods) (Copy).</p> <p>6. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>companies to notify the MIA every five years that they continue to exercise the same activity.</p> <p>4. Propose to the Ministry that the fee of EUR 500 applied for this procedure be calculated within the cost of this registration, to ensure compliance with Article 18 of the Law on Permit and License System.</p> <p>5. Amend Administrative Instruction No. 04/2013 on Criteria and Procedures for Licenses and Permits and Administrative Instruction (MIA) No. 07/2013 on UN Hazards Classification and Compatibility Groups in the respective sections where the licensing obligation is determined so that the registration and notification obligation is determined.</p> <p>6. Amend Administrative Instruction No. 04/2013 on Criteria and Procedures for Licenses and Permits and Administrative Instruction (MIA) No. 07/2013 on UN Hazards</p>	<p>required that they be registered in the Ministry of Infrastructure according to Article 7 of the Law on Permit and License System. And at the time of registration of the company, this registration serves for all three types of activity (manufacturing, import/export/transfer and use). With the current regulation, the legal person is obliged to pay EUR 500 for each license (i.e., 3 x EUR 500), and for the same to apply every 5 years. Such payment is a very heavy administrative burden for legal persons that want to exercise this activity, given that this licensing procedure does not offer the possibility to start exercising the activity.</p> <p>2. Since by registration the legal person is already part of the register of the MIA, for security purposes, based on Article 6 of the Law on Permit and License System, the legal person may notify the competent authority that it continues to exercise the same activity every 5 years. The same cannot be registered for the second time since it is already registered.</p>

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						<p>Classification and Compatibility Groups to abolish the obligation to submit: (i) Certificates of authorized persons and (ii) Certificates of qualified persons. Also, abolish the requirement to submit: (i) Driving Certificate (special driving license for transport of dangerous goods) (Copy).</p> <p>7. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500 reflects the costs incurred by the authority in this procedure.</p> <p>4. Since Law No. 04/L-022 on Civil Use of Explosives will be amended, the same amendments should be reflected in the Administrative Instruction No. 04/2013 on Criteria and Procedures for Licenses and Permits and Administrative Instruction (MIA) No. 07/2013 on UN Hazards Classification and Compatibility Groups so as to abolish the obligation to obtain three different licenses with 5 years validity.</p> <p>5. Documents such as (i)</p>

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							<p>Certificates of authorized persons and (ii) Certificates of qualified persons), as well as (i) Driving Certificate (special license for driving vehicles for transport of dangerous goods) (Copy) are documents issued by the MIA to the legal person. Therefore, it is meaningless and unnecessary to require from the legal person to submit them during this procedure. This represents an unnecessary additional cost for the applicant.</p> <p>6. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DSP2	<p>1. Permit for import, export, transit or transfer of explosives and fireworks;</p> <p>2. Permit for retail shop to sell fireworks;</p> <p>3. Permit for</p>	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Law No. 04/L-022 on Civil Use of Explosives treats explosives and fireworks as the same category. Such arrangement is contrary to Directive 2013/29/EU of the European Parliament and Directive 2014/28/EU of the European Parliament.</p>	<p>1. Amend in entirety Law No. 04/L-022 on Civil Use of Explosives, so that explosives and fireworks are regulated as separate categories.</p> <p>2. Amend current law so that for each category the following permits are required for the</p>	<p>1. The division into two separate categories of explosives and fireworks is done in accordance with the EU Directives and in accordance with the degree of risk associated with explosives and fireworks. Such practice is also followed in Montenegro, where a clear distinction is</p>

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		storage; 4. Permit for destruction; 5. Permit for manufacturing; 6. Permit for use of fireworks; 7. Permit for manufacturing building; 8. Permit for use (blast permit);			2. Law No. 04/L-022 on Civil Use of Explosives and Administrative Instruction No. 04/2013 on Criteria and Procedures for Licenses and Permits stipulate that when applying for a permit for import, export, transit or transfer of explosives and fireworks, the legal person must also submit documents such as: i) Copy of the relevant permit for sale, manufacturing or use of explosives and fireworks (Copy) and (ii) Certificate of professional qualification (relevant experience) (Copy); for a permit for retail sale of fireworks, the legal person must submit documents such as: Copy of the storage permit and Copy of the certificate of qualified persons (Certified copy); for a storage permit, the legal person is obliged to submit documents such as: Copy of the relevant permit for sale, manufacturing or use of explosives and fireworks (Copy) and Certificate of professional qualification (relevant experience) (Copy); for the permit for destruction, the legal person is obliged to submit documents such as: Copy of license and Certificate of professional qualification (relevant experience) (Copy); for manufacturing permit,	exercise of their activity: 1. Permit for import, export, transit or transfer, sale, storage and manufacturing of explosives; 2. Permit for use of explosives; 3. Permit for destruction of explosives; 4. Permit for import, export, transfer, retail sale, manufacturing of fireworks; 5. Permission for use of fireworks; 6. Permit for destruction of fireworks; 3. Amend Law No. 04/L-022 on Civil Use of Explosives and Administrative Instruction No. 04/2013 on Criteria and Procedures for Licenses and Permits, so that the following documents are not required for the following permits: - Permit for import, export, transit or transfer of explosives and fireworks, the legal person must also submit documents such as: i) Copy of the relevant permit for sale, manufacturing or use of explosives and fireworks (Copy) and (ii) Certificate of professional qualification (relevant experience) (Copy);	made between these categories. 2. Permits for import, export, transit or transfer, sale, storage and manufacturing of explosives and fireworks respectively should be merged into a single permit because the same criteria apply to both. On the other hand, the permit for the use of explosives on the one hand and the permit for the use of fireworks should be separate permits due to the conditions and criteria that must be met for each. The same reasoning applies to permits for destruction. 3. With the current regulation, the legal person must apply 8 times to obtain each of these permits. 3. The abolition of the obligation to submit documents issued by the MIA as different types of permits and different certificates is done for reasons of non-existence of the need for legal persons to submit these documents to the same entity that issued them. Such practice creates a great administrative burden for businesses and is completely meaningless. Also, by merging 8 permits into 3,

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					<p>the legal person is obliged to submit documents such as: Certificates of authorized persons and Certificates of qualified persons; for Permit for use of fireworks, the legal person is obliged to submit documents such as: Certificate of professional qualification (relevant experience) (Copy), Certificate of authorized persons (Copy), Identity card (Copy); for the Permit for manufacturing building, the legal person is obliged to submit documents such as: Copy of license for use of explosives or fireworks or Copy of license for manufacturing of explosives or fireworks (Copy), Certificate of professional qualification (relevant experience) (Copy), Location of Safety Plan and Risk Assessment. (Copy); for the Permit for use (blast permit), the legal person is obliged to submit documents such as: Certificate of professional qualification (relevant experience) (Copy), Certificate of authorized persons (Copy), Identity card.</p> <p>3. The appeals procedure is not regulated in accordance with the provisions of the LGAP.</p>	<ul style="list-style-type: none"> - Permit for retail sale of fireworks, the legal person must submit documents such as: Copy of storage permit and Copy of certificate of qualified persons (Certified copy); - Permit for storage, the legal person is obliged to submit documents such as: Copy of the relevant permit for sale, manufacturing or use of explosives and fireworks (Copy) and Certificate of professional qualification (relevant experience) (Copy); - Permit for destruction, the legal person is obliged to submit documents such as: Copy of license and Certificate of professional qualification (relevant experience) (Copy); - Permit for manufacturing, the legal person is obliged to submit documents such as: Certificates of authorized persons and Certificates of qualified persons; - Permit for the use of fireworks, the legal person is obliged to submit documents such as: Certificate of professional qualification (relevant experience) (Copy), Certificate of authorized persons (Copy), Identity card (Copy); 	<p>they are integral to each other.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>

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						<p>- Permit for manufacturing building, the legal person is obliged to submit documents such as: Copy of license for use of explosives or fireworks or Copy of license for manufacturing of explosives or fireworks (Copy), Certificate of professional qualification (relevant experience) (Copy), Location of Safety Plan and Risk Assessment. (Copy);</p> <p>- Permit for use (blast permit), the legal person is obliged to submit documents such as: Certificate of professional qualification (relevant experience) (Copy), Certificate of authorized persons (Copy), Identity card.</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	
Ministry of Internal Affairs	DSP3	<p>Authorization for commencing operations of Private Security Company</p> <ul style="list-style-type: none"> • Authorization for commencing operations of 	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Authorization for commencing operations of the Private Security Company, according to the Law on Permit and License System, meets all legal criteria to be recognized as Notice. 2. Decision of the Minister No. 154/2016 on Setting of Fees dated 30.05.2016, abrogated by Decision No. 328/2016 dated</p>	<p>1. Amend Articles 23 and 24 of Law No. 04/L-004 on Private Security Services, so that the Authorization for commencing operations of the private security company is named as the Notice for the commencing operations of the private security company; 2. Amend</p>	<p>1. The authorization for commencing operations of the private security company fulfills all the conditions defined in Article 6, paragraph 2 of Law No. 04/L-202 on Permit and License System. Therefore since Law No. 04/L-202 on Permit and License System does not recognize the</p>

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		<p>Basic Security Services</p> <ul style="list-style-type: none"> • Authorization for commencing operations of Close Protection Services • Authorization for commencing operations of CIT Services • Authorization for commencing operations of Electronic Property Surveillance • Authorization for commencing operations of Security Services of Public Gatherings • Authorization for appointment of CPOs 			<p>16.11.2016 and Decision No. 394/2017 dated 15.12.2017 foresees the fee of EUR 20 for obtaining the Authorization for commencing operations of a private security company, which in essence is the notification of MIA on clients of the security company, so that the MIA knows who the clients of the company are.</p> <p>2. Decision No. 12/20 on Setting of Fees, dated 16.01.2020 specifies in Annex 2 five (5) types of authorization by service, with fees ranging from EUR 5 to EUR 20. This fee paid upon obtaining the authorization for commencing operations of Private Security Company is in essence a notice to the MIA on the clients of the security company which ensures the MIA is informed on the company's clients. The fees due for each authorization are as follows:</p> <ul style="list-style-type: none"> • Authorization for commencing operations of Basic Security Services (EUR 10) • Authorization for commencing operations of Close Protection Services (EUR 20) 	<p>Decision of the Minister No. 154/2016 on Setting of Fees dated 30.05.2016, abrogated by Decision No. 328/2016 dated 16.11.2016 - and by Decision No. 394/2017 dated 15.12.2017, in order to abolish the foreseen fee of of EUR 20 for notification.</p> <p>2. Amend Decision No. 12/20 on Setting of Fees, dated 16.01.2020 Annex 2, to abolish the foreseen fee of EUR 5-20 for notification purposes.</p> <p>3. Change the practice of the MIA for requesting a copy of the license of the company to perform the relevant services.</p>	<p>Authorization, then its name is changed to Notice as it serves the same purpose.</p> <p>2. While the removal of the administrative fee upon application is done in accordance with Article 18 of Law No. 04/L-202 on Permit and License System.</p> <p>3. The abolition of the obligation to submit a copy of the relevant license issued by the MIA is done for reasons of non-existence of the need for legal persons to submit these documents in the same place that issued them. This practice creates a great administrative burden for businesses and is completely meaningless.</p>

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					<ul style="list-style-type: none"> • Authorization for commencing operations of CIT Services (EUR 20) • Authorization for commencing operations of Electronic Property Surveillance (EUR 5) • Authorization for commencing operations of Security Services of Public Gatherings (EUR 5) • Authorization for appointment of CPOs (EUR 5) <p>3. During the application for obtaining the authorization for commencing operations, it is required to submit a document such as: Proof of licensing of the company to perform the relevant services (Copy)</p>		
Ministry of Internal Affairs	DSP4	Certification of Control Center	/	Ministry of Internal Affairs, Department of Public Safety	1. The certification of the control center is a criterion for issuing a license to a company for the provision of specialized security services, including cash in-transit services, security services of public gatherings, close protection services, and property electronic surveillance services. At the moment of receiving the license	1. Amend Articles 13 and 21 of the Law on Private Security Services and merge them. 2. Such a certificate should be removed from the register of permits and licenses. 2. Amend Decision No. 12/20 on Setting of Fees dated 16.01.2020, Annex 2, point 11,	1. This certificate is a criterion which must be met when the company obtains a license for the provision of specialized services. As such it should not be included in the register of permits and licenses. 2. The abolition of the payment for obtaining this certificate,

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					<p>from the competent body, the company can start providing the service immediately.</p> <p>2. Decision No. 12/20 on Setting of Fees dated 16.01.2020 in Annex 2 point 11 sets the payment of EUR 50 for obtaining this certificate.</p>	<p>in order to abolish the requirement to pay the fee of EUR 50 for obtaining this certificate.</p>	<p>which is a criterion for obtaining a license, is done because the financial cost of issuing it must be calculated as part of the financial cost for obtaining a license. The project can help calculate the cost.</p>
Ministry of Internal Affairs	DSP5	<p>1. License for Basic Security Worker;</p> <p>2. License for Close Protection Operative;</p> <p>3. License for CIT Guard;</p> <p>4. License for dog-handler;</p> <p>5. License for Electronic Surveillance Operator;</p> <p>6. License for Security Manager/Duty Officer</p>	/	Ministry of Internal Affairs, Department of Public Safety	<p>1. According to Article 14 of the Law on Private Security Services, companies that are licensed to provide services must also license their employees to provide those services. Whereas, in the case of licensing the company, the company submits the list of employees who have already been verified. Also, there is a legal obligation for the security company to inform the MIA about the movements of their staff.</p>	<p>1. Amend Article 14 of the Law on Private Security Services to abolish the requirement for licensing employees for the services provided by the company and for which the company is already licensed. More specifically, abolish the following licenses:</p> <p>1. License for Basic Security Worker;</p> <p>2. License for Close Protection Operative;</p> <p>3. License for CIT Guard;</p> <p>4. License for dog-handler;</p> <p>5. License for Electronic Surveillance Operator;</p> <p>6. License for Security Manager/Duty Officer</p>	<p>Such requirement is considered to be excessive and a great administrative and financial burden for the company and the relevant officials. When a company is licensed to provide protection services, it means that it meets the necessary criteria for obtaining a license. Therefore, the requirement to license employees individually following the licensing of the company is unnecessary and excessive. Such recommendation has also been supported and proposed by Ministry officials.</p>
Ministry of Internal Affairs	DSP6	Official identification cards	/	Ministry of Internal Affairs, Department of Public Safety	<p>1. Article 35 of the Law on Private Security Services provides for the need to equip all employees of security companies with cards issued by the Ministry.</p>	<p>1. Amend Article 35 of the Law on Private Security Services which provides for the need to equip all employees of security companies with cards issued by the Ministry. 2. Amend Article 9</p>	<p>Since every security employee is verified when licensing a private company, obtaining cards from the Ministry is not necessary. Such cards can be issued by the company itself to its employees.</p>

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					<p>2. Article 9 of Administrative Instruction No. 27/2011 on Licensing Procedures stipulates that private security employees should be equipped with official identification cards by the Ministry.</p> <p>3. The private security company submits a request to the competent body for identification cards for all their licensed security employees. After reviewing the case, the senior officer for standardization, training and licensing at the Department of Public Safety at the Ministry of Internal Affairs issues the company identification card for their security personnel.</p>	of Administrative Instruction 27/2011 on Licensing Procedures which stipulates that the Ministry shall provide official identification cards to private security employees.	
Ministry of Internal Affairs	DSP7	License for close protection services	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Law No. 04/L-004 on Private Security Services in Article 10, paragraph 1.2 provides for the License for Close Protection Services.</p> <p>2. Administrative Instruction No. 27/2011- MIA on Licensing Procedures stipulates that the legal person which applies for this license, must submit the following documents at the time of application: (i) copy of the license for basic security service manager (Copy) and the certificate of the Control Center.</p>	<p>1. Amend Law No. 04/L-004 on Private Security Services, Article 10, paragraph 1.2 which foresees the License for Close Protection Services, so that it foresees the Permit for Close Protection Services.</p> <p>2. Amend Administrative Instruction No. 27/2011- MIA on Licensing Procedures which stipulates that the legal person applying for this license, must submit the following documents at the time of application: (i)</p>	<p>1. The license for close protection services is changed to Permit for close protection services since it is issued to legal persons and meets all the criteria according to Article 8 of Law No. 04/L-202 on Permit and License System to be classified as a permit. On the other hand, the license is issued for professional activities to natural persons.</p> <p>2. The abolition of the obligation to submit a copy of the relevant license issued by the MIA for</p>

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					<p>3. Decision of the Minister No. 154/2016 on Setting of Fees, dated 30.5.2016 determines the fee of EUR 500 to be paid upon receipt of this license.</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>copy of the license for the manager of basic security services (Copy) and the certificate of the Control Center, so that the submission of these documents is no longer required.</p> <p>3. Propose to the Ministry to include the fee of EUR 500 for obtaining this license in the cost of the license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project. The cost should be calculated taking into account the administrative cost of issuing the certificate to the control center (see recommendation above).</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>security manager and of the requirement of submitting the certificate of the Control Center is recommended because there is no need for legal persons to submit these documents to the entity that issued them. Such practice creates a great administrative burden for businesses and is completely meaningless. Furthermore, based on the above recommendation, after the proposed amendment, the Basic Security Services Manager License will no longer be issued.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500 for the license and EUR 50 for the certificate of the control center reflects the costs incurred by the authority for granting this license.</p>

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							4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.
Ministry of Internal Affairs	DSP8	License for Cash in-Transit services (CIT)	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Law No. 04/L-004 On Private Security Services in Article 10, paragraph 1.3 provides for the License for Cash in-Transit Services (CIT).</p> <p>2. Administrative Instruction No. 27/2011- MIA on Licensing Procedures stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (i) copy of 5 licenses of employees of basic security, (ii) Copy of the basic security services manager license, (iii) Control Center certificate, (iv) accredited transport vehicle certificate and an accompanying vehicle.</p> <p>3. Decision of the Minister No. 154/2016 on Setting of Fees, dated 30.5.2016 determines the fee of EUR 500 to be paid upon receipt of this license.</p> <p>4. The appeal procedure is not</p>	<p>1. Amend Law No. 04/L-004 on Private Security Services, Article 10, paragraph 1.3, which provides for the License for Cash in-Transit Services (CIT), so that it provides for the Permit for Cash in-Transit (CIT) Services.</p> <p>2. Amend Administrative Instruction No. 27/2011- MIA on Licensing Procedures which stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (i) copy of 5 basic security workers' licenses, (ii) Copy of the basic security services manager license, (iii) Control Center certificate, (iv) Certificate of accredited transport vehicle and an accompanying vehicle, so that submission of these documents is no longer required.</p> <p>3. Propose to the Ministry to</p>	<p>1. The license for cash in-transit (CIT) services is changed to Permit for cash on-transit (CIT) services since it is issued to legal persons and meets all the criteria according to Article 8 of Law No. 04/L-202 on Permit and License System to be classified as a permit. On the other hand, the license is issued for professional activities to natural persons.</p> <p>2. Abolition of the obligation to submit (i) copy of 5 licenses of basic security workers, (ii) Copy of license for manager of basic security services, (iii) certificate of Control Center, (iv) certificate of vehicle accredited transporter and an accompanying vehicle, all documents issued by the MIA is recommended because it is not necessary for legal persons to submit these documents in the same place that issued</p>

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					regulated in accordance with the provisions of the LGAP.	<p>calculate the fee of EUR 500 for obtaining this license in the cost of the license, to ensure compliance with Article 18 of the Law on Licenses.</p> <p>The project can assist with this calculation. The cost should be calculated taking into account the administrative cost of issuing the certificate to the control center (see recommendation above).</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>them. Such practice creates a great administrative burden for businesses and is completely meaningless.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500 for the license and EUR 50 for the certificate of the control center reflects the costs incurred by the authority for administering this license.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DSP9	License for basic security services	Permit	Ministry of Internal Affairs, Department of Public Safety	1. Law No. 04/L-004 on Private Security Services in Article 10, paragraph 1.1 provides for the License for basic security services.	1. Amend Law No. 04/L-004 on Private Security Services in Article 10, paragraph 1.1 which provides for the License for basic security services, so that	1. License for basic security services is changed to Permit for basic security services since it is issued to legal persons and meets all the criteria under

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					<p>2. Administrative Instruction No. 27/2011- MIA on Licensing Procedures stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (i) copy of 5 licenses of employees of basic security, (ii) Copy of the license for manager for basic security services,</p> <p>3. Decision of the Minister No. 154/2016 on Setting of Fees, abrogated by Decision No. 328/2016 dated 16.11.2016 and Decision No. 394/2017 dated 15.12.2017, determines the fee of EUR 500 to be paid for obtaining this license and EUR 250 for renewing it.</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>the same provides for the Permit for basic security services.</p> <p>2. Amend Administrative Instruction No. 27/2011- MIA on Licensing Procedures which stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (i) copy of 5 licenses of basic security workers, (ii) Copy of the license for manager for basic security services, so that the submission of these documents is no longer required.</p> <p>3. Propose to the Ministry to calculate the fee of EUR 500 for obtaining this license and EUR 250 for renewing it within the cost of the license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>Article 8 of Law No. 04/L-202 on Permit and License System to be classified as a permit, while the license is issued for professional activities to natural persons.</p> <p>2. Abolition of the obligation to submit (i) a copy of 5 licenses of basic security workers, (ii) Copy of the license for manager of basic security services, all documents issued by the MIA, is done for reasons of non-existence of the need for legal persons to submit these documents to the same country that issued them. Such practice creates a great administrative burden for businesses and is completely meaningless.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500 for obtaining a license and EUR 250 for</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							<p>renewing it is in accordance with the law.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DSP10	License for Electronic Property Surveillance Services	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Law No. 04/L-004 on Private Security Services foresees in Article 10, paragraph 1.4 the License for electronic property surveillance services.</p> <p>1. Administrative Instruction No. 27/2011- MIA on Licensing Procedures stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (i) Copies of 5 licenses of electronic surveillance operators, (ii) Certificate of the Control Center</p> <p>2. Decision of the Minister No. 154/2016 on Setting of Fees, dated 30.5.2016 determines the fee of EUR 500 to be paid for obtaining this license and EUR 250 for renewing it.</p>	<p>1. Amend Law No. 04/L-004 On Private Security Services in Article 10, paragraph 1.1 which provides the License for electronic property surveillance services, so that the same provides for the License for electronic property surveillance services.</p> <p>1. Amend Administrative Instruction No. 27/2011- MIA on Licensing Procedures which stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (: (i) copy of 5 licenses of electronic surveillance workers, (ii) the certificate of the Control Center.</p> <p>2. Propose to the Ministry to</p>	<p>1. License for electronic property surveillance services changes to Permit for electronic property surveillance services since it is issued to legal persons and meets all criteria under Article 8 of Law No. 04/L-202 on Permit and License System to be a permit. While the license is for professional activities and is issued to natural persons.</p> <p>1. Abolition of the obligation to submit: (i) copy of 5 licenses of electronic surveillance workers, (ii) certificate of the Control Center, all documents issued by the MIA, is done for reasons of non-existence of the need that legal persons submit these documents to the same country that issued them. This practice creates a great administrative</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					3. The appeal procedure is not regulated in accordance with the provisions of the LGAP.	<p>calculate the fee of EUR 500 for obtaining this license and EUR 250 for renewing it within the cost of the license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project. The cost should be calculated taking into account the administrative cost of issuing the certificate to the control center (see recommendation above).</p> <p>3. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>burden for businesses and is completely meaningless.</p> <p>2. The fee that a competent authority may charge for a permission shall not exceed the amount (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500 for obtaining a license and EUR 250 for renewing it, as well as EUR 50 for the certificate of the control center is in accordance with the law.</p> <p>3. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DSP11	License for Security Services of Public Gatherings	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Law No. 04/L-004 on Private Security Services foresees in Article 10, paragraph 1.4 the License for security services of public gatherings.</p> <p>2. Administrative Instruction No. 27/2011- MIA on Licensing Procedures stipulates that the legal person who applies for this license,</p>	1. Amend Law No. 04/L-004 on Private Security Services, Article 10, paragraph 1.1, which provides for the License for Security Services of Public Gatherings, so that the same provides instead for the Permit Security Services of Public Gatherings.	1. License for security services of public gatherings is changed to the Permit for security services of public gatherings since it is issued to legal persons and meets all the criteria according to Article 8 of Law No. 04/L-202 on Permit and License System to be classified as a permit. On the other hand, the license is issued

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>must submit the following documents at the time of application: (i) Copies of 15 licenses of basic security workers; (ii) Certificate of Control Center</p> <p>3. Decision of the Minister No. 154/2016 on Setting of Fees, dated 30.5.2016, determines the fee of EUR 500 to be paid for obtaining the license and EUR 250 for renewing it.</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>2. Amend Administrative Instruction No. 27/2011- MIA on Licensing Procedures which stipulates that the legal person who applies for this license, must submit the following documents at the time of application: i) copy of 15 licenses of basic security workers, (ii) the certificate of the Control Center.</p> <p>3. Propose to the Ministry to calculate the fee of EUR 500 for obtaining the license and EUR 250 for renewing it within the cost of the license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project. The cost should be calculated taking into account the administrative cost of issuing the certificate to the control center (see recommendation above).</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>for professional activities to natural persons.</p> <p>2. Abolition of the obligation to submit: (i) copies of 15 licenses of basic security workers, (ii) the certificate of the Control Center, which are issued by the MIA is recommended because there is no need to require from legal persons to submit these documents to the entity that issued them. This practice creates a great administrative burden for businesses and is completely meaningless.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500 for obtaining a license and EUR 250 for renewing it, as well as EUR 50 for the certificate of the control center is in accordance with the law.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							handling complaints in any administrative procedure including the procedure concerned.
Ministry of Internal Affairs	DSP12	License for institution to provide basic professional training in the field of private security specialized in the field of private security	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Law No. 04/L-004 on Private Security Services foresees in Article 10, paragraph 1.4 the License for institution to provide basic professional training in the field of private security specialized in the field of private security.</p> <p>2. AI (MIA) No. 06/2012 on Training, Certification, Recertification and Licensing of Training Institutions determines that the legal person who applies for this license, must submit the following documents at the time of application: (i) Request for background checks for the applicant entity, founders, owners and responsible persons (Original), (ii) Certificate of qualified legal lecturer (Verified copy), (iii) Certificate of qualified first aid instructor (Copy of verified), (iv) Certificate of qualified instructor for fire prevention (Verified copy), (v) Certificate of qualified instructor for private security in each respective field (Original), (vi) Report of the competent body that the object I meets the prescribed criteria (Original), (vii) Copy of the contract</p>	<p>1. Amend Law No. 04/L-004 on Private Security Services, Article 10, paragraph 1.1 which provides for the License for institution for the provision of basic professional training in the field of private security specialized in the field of private security, so that it foresees instead a Permit for an institution for providing basic professional training in the field of private security specialized in the field of private security.</p> <p>2. Amend AI No. 06/2012- MIA on Training, Certification, Recertification and Licensing of Training Institutions to abolish the requirement for the legal person applying for this license to submit the following documents at the time of application: (i) Request for background checks for the applicant entity, founders, owners and responsible persons (Original), (ii) Certificate of qualified legal lecturer (Verified copy), (iii) Certificate of qualified first aid instructor (Verified copy), (iv) Certificate of qualified instructor for fire prevention (Verified copy), (v) Certificate of qualified instructor for private security in each respective field (Original), (vi) Report of the competent body that the object I meets the prescribed criteria (Original), (vii) Copy of the contract</p>	<p>1. License for an institution to provide basic professional training in the field of private security specialized in the field of private security is changed to a Permit for an institution for providing basic professional training in the field of private security specialized in the field of private security since it is issued to legal persons and meets all the criteria under Article 8 of Law No. 04/L-202 on Permit and License System to be classified as a permit. On the other hand, the license is issued for professional activities to natural persons.</p> <p>2. Abolition of the obligation to submit: ((i) Request for background checks for the applicant entity, founders, owners and responsible persons (Original), (ii) Certificate of qualified legal lecturer (Verified copy), (iii) Certificate of qualified first aid instructor (Verified copy), (iv) Certificate of qualified instructor for fire</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>of the contract manager (Verified copy).</p> <p>3. Decision of the Minister No. 154/2016 on Setting of Fees, dated 30.5.2016 determines the fee of EUR 500 to be paid on the occasion of obtaining this license and 250 for the continuation of the same</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>first aid instructor (Verified copy), (iv) Certificate of qualified fire prevention instructor (Verified copy), (v) Certificate of qualified private security instructor for each relevant field (Original), (vi) Report of the competent body that the facility meets the prescribed criteria (Original), (vii) Copy of the contract of the contract manager (Verified copy).</p> <p>3. Propose to the Ministry to calculate the fee of EUR 500 for obtaining the license and EUR 250 for renewing it within the cost of the license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>prevention (Verified copy), (v) Certificate of qualified instructor for private safety in each relevant field (Original), (vi) The report of the competent body that the facility meets the prescribed criteria (Original), which are issued by the MIA is recommended because there is no need to require from legal persons to submit these documents to the entity that issued them. This practice creates a great administrative burden for businesses and is completely meaningless. In addition, abolition of the requirement to submit a copy of the manager's contract (certified copy) is recommended as this constitutes an administrative burden for the applicant. A simple copy could serve the same purpose.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission. (Article 18 of the Law on Permit and License System). The project can assist</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							<p>with this calculation, as well as with the analysis whether the fee of EUR 500 for obtaining a license and EUR 250 for its renewal is in accordance with the law.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DSP13	License for an institution to provide basic professional training in the field of private security	Permit	Ministry of Internal Affairs, Department of Public Safety	<p>1. Law No. 04/L-004 on Private Security Services foresees in Article 10, paragraph 1.4 the License for an institution to provide basic professional training in the field of private security.</p> <p>2. Administrative Instruction No. 27/2011- MIA on Licensing Procedures stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (i) Request for background checks for the applicant entity, founders, owners and responsible persons (Original), (ii) Certificate of qualified legal lecturer (Certified copy), (iii) Certificate of qualified first aid instructor</p>	<p>1. Amend Law No. 04/L-004 on Private Security Services, Article 10, paragraph 1.1, which foresees the License for an institution to provide basic professional training in the field of private security, so that it foresees instead the Permit for an institution to provide basic professional training in the private field of security.</p> <p>2. Amend Administrative Instruction No. 27/2011- MIA on Licensing Procedures, which stipulates that the legal person who applies for this license, must submit the following documents at the time of application: (i) Request for</p>	<p>1. The license for an institution to provide basic professional training in the field of private security is changed to Permit for an institution for providing basic professional training in the field of private security since it is issued to legal persons and meets all criteria under Article 8 of Law No. 04/L-202 on Permit and License System to be classified as a permit. On the other hand, the license is issued for professional activities to natural persons.</p> <p>2. Abolition of the obligation to submit: (i) Request for background checks for the applicant entity, founders,</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>(Certified copy), (iv) Certificate of qualified fire prevention instructor (Certified copy), (v) Certificate of qualified private safety instructor in each respective field (Original), (vi) Report of the competent body that the facility meets the prescribed criteria (Original) .</p> <p>3. Decision of the Minister No. 154/2016 on Setting of Fees, dated 30.5.2016 determines the fee of EUR 500 for obtaining the license and EUR 250 for renewing it.</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>background checks for the applicant entity, founders, owners and responsible persons (Original), (ii) Certificate of qualified legal lecturer (Certified copy), (iii) Certificate of qualified first aid instructor (Certified copy), (iv) Certificate of qualified fire prevention instructor (Certified copy), (v) Certificate of qualified private safety instructor in each respective field (Original), (vi) Report of the competent body that the facility meets the criteria of foreseen (Original).</p> <p>3. Propose to the Ministry to calculate the fee of EUR 500 for obtaining the license and EUR 250 for renewing it in the cost of this license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>owners and responsible persons (Original), (ii) Certificate of qualified legal lecturer (Certified copy), (iii) Certificate of qualified first aid instructor (Certified copy), (iv) Certificate of qualified fire prevention instructor (Certified copy), (v) Certificate of qualified private safety instructor in each respective field (Original)), (vi) The report of the competent body that the facility meets the prescribed criteria (Original), which are issued by the MIA, is recommended because it is not necessary to require from legal persons to submit these documents to the same entity that issued them. This practice creates a great administrative burden for businesses and is completely meaningless.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission. (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							<p>with the analysis whether the amount of EUR 500 for obtaining a license and EUR 250 for renewing it is in accordance with the law.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DSP14	License for shooting ranges	Permit	Ministry of Internal Affairs, DAME	<p>1. Law No. 05/L -022 on Weapons foresees in Article 64 the License for civil shooting ranges.</p> <p>2. AI (MIA) No. 10/2010 Regarding Minimum Technical and Security to be Met in the Premises of Civil Shooting Ranges determines that the legal person applying for this license must submit the following documents to apply: (i) Evidence from the competent body of possession of space for safe storage and placement of firearms and ammunition, (ii) Number of certified and registered workers (Copy), (iii) Certificates of construction materials used (Copy).</p> <p>3. A fee of EUR 500 must be paid for obtaining this license, and a fee of</p>	<p>1. Amend Law No. 05/L-022 on Weapons Article 64 which foresees the License for civil shooting ranges so that the same foresees instead the Permit for civilian shooting ranges.</p> <p>2. Amend AI (MIA) No. 10/2010-Regarding Minimum Technical and Security to be Met in the Premises of Civil Shooting Ranges and abolish the requirement for the legal person applying for this license to submit the following documents: (i) Evidence from the competent body of possession of space for safe storage and placement of firearms and ammunition, (ii)</p>	<p>1. The license for civil shooting ranges is changed to Permit for civil shooting ranges, since it is issued to legal persons and meets all criteria under Article 8 of Law No. 04/L-202 on Permit and License System to be classified as permit. On the other hand, the license is issued for professional activities to natural persons.</p> <p>2. Abolition of the obligation to submit (i) Evidence from the competent body of possession of space for safe storage and placement of firearms and ammunition, (ii) Number of certified and registered workers (Copy), (iii) Certificates of construction materials used</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>EUR 250 for renewing it.</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>Number of certified and registered workers (Copy), (iii) Certificates of construction materials used (Copy).</p> <p>3. Propose to the Ministry to calculate the fee of EUR 500 for obtaining this license and EUR 250 for renewing it in the cost of this license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>(Copy), which are issued by the MIA, is recommended because it is not necessary to require legal persons to submit these documents to the same entity that issued them. This practice creates a great administrative burden for businesses and is completely meaningless.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the amount of EUR 500 for obtaining a license and EUR 250 for renewing it is in accordance with the law.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry of Internal Affairs	DAME1	<p>Authorization on requirements for fire protection advancement work, with nine categories of authorizations issued:</p> <ul style="list-style-type: none"> - Authorization for carrying out studies on fire protection organization - Authorization for carrying out analyzes of the existing fire protection situation - Authorization for the development of fire protection improvement and advancement programs - Authorization for carrying out analyzes of dangerous areas and the definition 	Professional license	Ministry of Internal Affairs, EMA	<p>1. Paragraph 5 of Article 19 of Law No. 04/L-012 on Fire Protection states that "Control of regularity and servicing of apparatus may be practiced by authorized persons who are technically and professionally trained, according to the authorization of the Ministry-Agency. While Administrative Instruction No. 25/2012 on requirements for fire protection advancement work specifies 9 categories in Article 1</p> <p>2. For these authorizations that are already issued by the MIA, the parties pay the amount of EUR 250 for each.</p>	<p>1. Amend Article 19, paragraph 5, of the Law on Private Security Services, So that it lays down the need for professional licensing of natural persons applicable to all categories, instead of their authorization. Add this professional license in the register.</p> <p>2. Propose to the Ministry that the fee of 9 x EUR 250 to obtain this license be calculated within the cost for obtainin it, to ensure compliance with Article 18 of the Law on Permit and License System. This calculation can be done by the project.</p>	<p>1. These authorizations meet all the requirements of a professional license under Article 9 of the Law on Permit and License System. This law does not recognize the term authorization.</p> <p>2. The proposal to merge the 9 authorizations aims at reducing the administrative burden and is based on their redundancy.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis if the fee of 9 x EUR 250 for a license is in accordance with the law.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
		<p>of these areas in places endangered by the occurrence of explosive mixtures</p> <ul style="list-style-type: none"> - Authorization for the design of apparatus and installations for fire detection, notification and extinguishing - Authorization for testing the earthing resistance in lightning installations - Authorization for testing physical-chemical properties of flammable solids, liquids and gases, as well as the suitability of use of all substances in facilities with fire risk; - Authorization for the development 					

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
		<p>of trainings for the preparation of candidates for passing the professional exam for work with dangerous substances</p> <p>- Authorization for the development of trainings for the preparation of candidates for passing the professional exam in the field of fire protection</p>					
Ministry of Internal Affairs	DAME2	On-site consent for the construction of facilities for hazardous substances (landfills, gas stations)	Permit	Ministry of Internal Affairs, EMA	<p>1. Law No. 04/L-012 on Fire Protection does not explicitly acknowledge this consent.</p> <p>2. In order to obtain this consent, the following document must be submitted: (i) Fire protection plan (Elaborate) (Copy)</p> <p>3. For obtaining this consent, a payment of EUR 150 is required for obtaining the consent and EUR 50 for the site visit.</p> <p>4. The appeal procedure is not regulated in accordance with the</p>	<p>1. This consent should not be part of the register.</p> <p>2. Abolish the requirement and change the practice of requesting the document known as: (i) Fire protection plan (Elaborate) (Copy).</p> <p>3. Propose to the Ministry to calculate the fee of EUR 150 for obtaining consent and EUR 50 for the field visit within the cost of this consent, to ensure compliance with Article 18 of the Law on Licenses.</p>	<p>1. This consent should not be included in the register as it should be part of the procedure for obtaining a construction permit. The same serves neither as a notice, nor as a registration, nor as a permit, nor as a professional license within the criteria of Law No. 04/L-202 on Permit and License System.</p> <p>2. Abolition of the obligation to submit the document known as: (i) Fire protection plan (Elaborate) (Copy) is recommended because it is not</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					provisions of the LGAP.	<p>This calculation can be done by the project.</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>necessary to require legal persons to submit these documents to the entity that issued them. This practice creates a great administrative burden for businesses and is completely meaningless.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission. (Article 18 of the Law on Permit and License System). Furthermore, the same must be taken into account during the process of obtaining the construction permit.</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DAME3	Consent for investment-technical documentation (projects) on fire protection	/	Ministry of Internal Affairs, EMA	<p>1. Law No. 04/L-012 on Fire Protection does not explicitly acknowledge this consent.</p> <p>2. For obtaining this consent, a payment of EUR 150 is required for</p>	<p>1. This consent should not be part of the register.</p> <p>2. Propose to the Ministry to calculate the fee of EUR 150 for obtaining the consent and EUR</p>	<p>1. This consent should not be part of the register since it does not serve as a notification, a registration, a permit or a professional license within the criteria of Law No. 04/L-202 on</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
		measures			<p>obtaining the consent and EUR 50 for the field visit.</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>50 for the field visit within the cost of this consent, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p> <p>3. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>Permit and License System.</p> <p>2. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission. (Article 18 of the Law on Permit and License System). Furthermore, the same must be taken into account during the process of obtaining the construction permit.</p> <p>3. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>
Ministry of Internal Affairs	DAME4	Certificate for passing the professional fire protection exam	Professional license	Ministry of Internal Affairs, EMA	<p>1. Law No. 04/L-012 on Fire Protection does not explicitly provide for this certificate.</p> <p>2. Administrative Instruction (MIA) No. 16/2017 on Preparing Candidates for Passing the Professional Exam in the Area of Fire Protection provides that the candidate must submit the following documents when applying for a certificate: (i) Identification</p>	<p>1. Change the name from Certificate for passing the professional fire protection exam to License for fire protection.</p> <p>2. Amend Administrative Instruction (MIA) No. 16/2017 on Preparing Candidates for Passing the Professional Exam in the Area of Fire Protection in order to abolish the</p>	<p>1. The function of this certificate is the training of candidates/natural persons for fire protection. Therefore, the same is a professional license under Article 9 of Law No. 04/L-202 On Permit and License System.</p> <p>2. Abolition of the obligation to submit the following documents: (i) Identification</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>card (Copy), (ii) Birth certificate (Copy), (iii) Proof of special training (Copy).</p> <p>3. A fee of EUR 150 must be paid for obtaining this license.</p> <p>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</p>	<p>requirement of the candidate to submit the following documents when applying for a certificate: (i) Identification card (Copy), (ii) Birth Certificate (Copy), (iii) Proof of special training (Copy).</p> <p>3. Propose to the Ministry that the fee of EUR 150 for obtaining the certificate be calculated within the cost of obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p> <p>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</p>	<p>card (Copy), (ii) Birth Certificate (Copy), (iii) Proof of special training (Copy) is recommended because it is not necessary to require the legal persons to submit these documents to the same entity that issued them. This practice creates a great administrative burden for businesses and is completely meaningless.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System).</p> <p>4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.</p>

Simplification of Infrastructure Sector permits and licenses at the Ministry of Environment, Spatial Planning and Infrastructure (MESPI)

In the process of simplifying permits and licenses for the infrastructure sector in the Ministry of Environment, Spatial Planning and Infrastructure (MESPI) and harmonizing them with Law No. 04/L-202 on Permit and License System, a total of 38 permits and licenses were analyzed. More precisely, these 38 permits and licenses include: fifteen (15) procedures that fall within the scope of the Department of Vehicles, two (2) procedures that fall within the scope of the Department of Civil Aviation, twenty (20) procedures that fall within the scope of the Department of Transport, and one (1) procedure that fall within the scope of the Department of Road Management.

During the analysis process, special focus was given to the legal basis of all relevant permits and licenses issued within the MESPI for infrastructure issues, the procedure followed by the relevant departments, the documents required and the form of submitting them. Further, the flow of applications for relevant permits and licenses and the flow of permits issued by the MESPI for the infrastructure sector were also

analyzed during the research. Moreover, the necessity of the existence of the permits and licenses, the function they perform as well as the possibility of simplifying them in terms of required documentation and payments were also studied and evaluated during the analysis. At the same time, in the process of simplification, the possibility of merging some of them and removing them from the existing procedures within the Ministry was analyzed. During the analysis process, legal persons/businesses and companies exercising respective functions concerning which such permits and licenses are required were also consulted. During these meetings, the administrative burden that these procedures create for these businesses was discussed, as well as their necessity in the context of the risk associated with respective activities, including the applicable standards (where they exist) of the European Union or member states with comparable characteristics.

Of the 38 procedures analyzed, for four (4) of them it was proposed to abolish the re-certification procedure, ten (10) of them were proposed to be removed from the register, three (3) of them were merged into one (1), while for all it is proposed to simplify the procedures by reducing the requirement for submitting documents issued by the Ministry itself and lowering applicable fees.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry of Environment, Spatial Planning and Infrastructure	DA1	Licence of driving school	Permit	MESPI - Department of Vehicles	1. Law No. 05/L-064 on Driving License stipulates in Article 6 that the Driving School is issued a license for categories A, B, C1, C1 + E, C, C + E, D, or D + E after it has met the conditions and the criteria provided by Law,	1. Amend Article 6 of Law No. 05/L-064 on Driving License so that the License of driving school is transformed into Permit of driving school. Second, amend this Article so as to allow obtaining a permit for two or more categories with one	The change from License to Permit is based on Article 8 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit may be required by a competent authority for an activity that poses a medium or high risk to public health, public safety or the environment, which is not regulated by a professional license. And in this case, we are dealing with a permit

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					<p>and that this license is issued only for one (1) category, which is valid for five (5) years, with the possibility of renewal.</p> <p>2. When applying for licensing for two or more categories, a driving school must complete the forms and provide the required documents for each category separately, although most of them are the same.</p> <p>3. The applying driving schools must pay a fee of EUR 50 for each category, in accordance with paragraph 1.9 of Article 11 of Administrative</p>	<p>procedure and to determine that the validity of the permit is permanent and not 5 years, i.e. temporary. In case the Driving School initially receives the permit only for one category, at the moment it requests permission for other categories as well, it should only add the necessary documents for the other category or categories and not start the procedure from the beginning.</p> <p>2. Amend paragraph 1.9 of Article 11 of Administrative Instruction (MI) No. 20/2017 on Licensing of Driving Schools so that the fee of EUR 50 per procedure is not required.</p> <p>3. Propose to the</p>	<p>and not a professional license which is issued to a natural person. Second, in the case of merging the admission procedure into a single one, the applicant is relieved of the burden of providing the same documents for each category. In case the applicant receives the permit only for one category and in the future, he wants to be licensed for other categories, he offers only the evidence of fulfillment of the conditions provided by law and does not duplicate documents that are already in the Ministry with the existence of permit categories proving their existence. Such a fusion of the procedure, in addition to easing the administrative burden of an applicant, also facilitates the work of the responsible officials. Furthermore, since the driving school has already proved that it meets the criteria for obtaining a permit, the re-permit procedure should be completely abolished. For</p>

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					<p>Instruction (MI) No. 20/2017 on Licensing of Driving Schools.</p> <p>4. The license is valid only for five (5) years, obliging the driving schools to go through the same procedure every 5 years, filling in the forms for each category and making the payment of the procedure for each category.</p> <p>4. The fee paid for obtaining this license ranges from EUR 100 to EUR 500.</p>	<p>Ministry that the fee of EUR 100 - 500 for obtaining this permit be calculated within its cost, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>this purpose, control mechanisms should be developed that ensure that the entity that holds a permit continues to meet the legal criteria for the permit it holds. In this way, the administrative and financial burden of the driving school and the relevant institutional officials is alleviated. Further, the applicable fee for obtaining a permit is abolished in accordance with the provision of Article 18 of the Law on Permits and Licenses.</p> <p>The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation.</p>

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Ministry of Environment, Spatial Planning and Infrastructure	DA2	Licence for professional lecturer in driving school	Professional Licence	MESPI - Department of Vehicles	<p>1. Law No. 05/L-064 on Driving License stipulates in Article 10, paragraph 2, that the license for professional lecturer is issued with a validity of five (5) years, with the possibility of renewal.</p> <p>2. The documents required to apply include the Certificate for basic training, while the law recognizes this only as a criterion.</p> <p>3. Article 31 of AI No. 04/2018 regulates the appeal procedure, which is not in accordance with the LGAP.</p>	<p>1. Amend Article 10, paragraph 2, of Law No. 05/L-064 on Driving License so that it is determined that the validity of the license is permanent and not 5 years.</p> <p>2. Change the practice of requiring submission of the Certificate for basic training during applications for a license.</p> <p>3. Amend Article 31 of AI No. 04/2018 and regulate the appeal procedure in accordance with the LGAP.</p> <p>4. Propose to the Ministry that the fee of EUR 250 paid for basic training and the fee of EUR 100 for obtaining this license be calculated within</p>	<p>The relicensing requirement is unnecessary considering the fact that the applicant, following licensing and commencement of activity of professional lecturer, during the 5-year period trains hundreds of candidates who then receive a permanent driving license. Therefore, the requirement that he/she undergo the same examinations and administrative procedures every five (5) years is difficult to understand and objectively unnecessary considering the five (5) year expertise that he/she acquires following licensing. In case of abolition of the obligation to renew the license and recognition of the permanent validity of the license for professional lecturer, the fee of EUR 50 for renewing the candidate's license is avoided.</p> <p>2. The Certificate for basic training is issued by MESPI or any licensed operator of the Ministry. The applicant should be spared the additional administrative</p>

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					4. The fee for basic training for professional lecturers in driving school is EUR 250.	the cost of the training, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.	burden for submitting duplicate documents issued by the Ministry itself. 4. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether EUR 250 + EUR 100 reflects the costs that the authority covers during the organization of training and licensing.
Ministry of Environment, Spatial Planning and Infrastructure	DA3	Licence for driver instructor	Professional Licence	MESPI - Department of Vehicles	1. Law No. 05/L-064 on Driving License stipulates in Article 18, paragraph 1, that the license for driver instructor is issued with a validity of five (5) years, with the possibility of renewal.	1. Amend Article 18, paragraph 1, of Law No. 05/L-064 on Driving License so that it determines that the validity of the license is permanent and not 5 years, and lays down the requirement for completing mandatory training.	The relicensing requirements is unnecessary considering the fact that the applicant, following licensing and commencement of activity of driver instructor, during the 5-year period trains hundreds of candidates who then receive a permanent driving license. Therefore, the requirement that he/she undergo the same examinations and administrative procedures

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					<p>2. Amend Article 4 of Administrative Instruction (MI) No. 19/2017 on Driver Instructor, which requires that applicants submit their certificate, diploma or instructor's permit.</p> <p>3. The appeal procedure is not in accordance with the LGAP.</p> <p>4. The fee for basic training for professional lecturers in driving school is EUR 250.</p>	<p>2. Amend Article 4 of Administrative Instruction (MI) No. 19/2017 on Driver Instructor, which requires that applicants submit their certificate, diploma or instructor's permit.</p> <p>2. Regulate the appeal procedure in accordance with the LGAP.</p> <p>4. Propose to the Ministry that the fee of EUR 250 paid for basic training and the fee of EUR 100 for obtaining this license be calculated within the cost of the training, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>every five (5) years is difficult to understand and objectively unnecessary considering the five (5) year expertise that he/she acquires following licensing. In this regard, it is suggested to require by law completion of mandatory training. In case of abolition of the obligation to renew the license and recognition of the permanent validity of the license for driver instructor, the fee of EUR 50 for renewing the candidate's license is avoided.</p> <p>2. The Certificate for driving license trainer is issued by MESPI or any licensed operator of the Ministry. The applicant should be spared the additional administrative burden for submitting duplicate documents issued by the Ministry itself.</p> <p>4. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the</p>

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							permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether EUR 250 reflects the costs that the authority incurs during the organization of training and licensing.
Ministry of Environment, Spatial Planning and Infrastructure	DA4	Licence for driving examiner	Professional Licence	MESPI - Department of Vehicles	<p>1. Law No. 05/L-064 on Driving License stipulates in Article 36 that the license for driving examiner is issued to the person that shows positive results in licensing exam for examiners and is valid for three (3) years, with the possibility of renewal of the license.</p> <p>2. The documents required to apply include the Certificate for</p>	<p>1. Amend Article 36 of Law No. 05/L-064 on Driving License so that it foresees that the validity of the license is permanent and not 3 years.</p> <p>2. Change the practice of requesting a Certificate of driving license trainer when applying for a License.</p> <p>3. Regulate the appeal procedure in accordance with the LGAP.</p> <p>4. Propose to the Ministry that the</p>	The relicensing requirement is unnecessary considering the fact that the applicant, following licensing and commencement of activity of driving examiner, during the 3-year period trains hundreds of candidates who then receive a permanent driving license. Therefore, the requirement that he/she undergo the same examinations and administrative procedures every three (3) years is difficult to understand and objectively unnecessary considering the three (3) year expertise that he/she acquires following licensing. In case of abolition of the obligation to renew the license and recognition of the permanent validity of the license for driving examiner,

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					<p>driving license trainer, while the law recognizes this only as a criterion.</p> <p>3. Article 31 of Administrative Instruction No. 08/16 on Examiners regulates the appeal procedure, which is not in accordance with the LGAP.</p> <p>4. When applying for this license, the applicant pays for the theoretical and practical exam, as well as additional fees of EUR 100 for licensing and relicensing each.</p>	<p>fee of EUR 100 paid for licensing and relicensing be calculated within the cost of obtaining this license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>the fee of EUR 100 for renewing the candidate's license is avoided.</p> <p>2. The Certificate for driving license trainer is issued by MESPI or any licensed operator of the Ministry. The applicant should be spared the additional administrative burden for submitting duplicate documents issued by the Ministry itself.</p> <p>4. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 100 reflects the costs that the authority incurs during the organization of training and licensing.</p>

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Ministry of Environment, Spatial Planning and Infrastructure	DA5	Licence for theoretical examiner	Professional license	MESPI - Department of Vehicles	<p>1. Law No. 05/L-064 on Driving License stipulates in Article 36 that the License for theoretical examiner is issued to the person who shows positive results in licensing exam for examiners and is valid for three (3) years with the possibility of renewal of the license.</p> <p>2. The documents required to apply include the Certificate for driving license trainer, while the law recognizes this only as a criterion.</p> <p>3. When applying for this</p>	<p>1. Amend Article 36 of Law No. 05/L-064 on Driving License so as to determine that the validity of the license is permanent and not 3 years.</p> <p>2. Change the practice of requesting a Certificate of driving license trainer when applying for a License.</p> <p>3. Propose to the Ministry that the fee of EUR 100 paid for licensing and re-licensing be calculated within the cost of obtaining this license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>1. The relicensing requirement is unnecessary considering the fact that the applicant, following licensing and commencement of activity of theory examiner, during the 3-year period trains hundreds of candidates who then receive a permanent driving license. Therefore, the requirement that he/she undergo the same examinations and administrative procedures every three (3) years is difficult to understand and objectively unnecessary considering the three (3) year expertise that he/she acquires following licensing. In case of abolition of the obligation to renew the license and recognition of the permanent validity of the license for theory examiner, the fee of EUR 100 for renewing the candidate's license is avoided.</p> <p>2. The Certificate for driving license trainer is issued by MESPI or any licensed operator of the Ministry. The applicant should be spared the additional administrative</p>

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					license, the applicant pays for the theoretical and practical exam, as well as additional fees of EUR 100 for licensing and relicensing each.		<p>burden for submitting duplicate documents issued by the Ministry itself.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 100 reflects the costs that the authority incurs during the organization of training and licensing.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DA6	Authorization for holding trainings and seminars for driving instructors	Permit	MESPI - Department of Vehicles	1. Law No. 05/L-064 on Driving License stipulates in Article 21 that entities authorized by respective Ministry of Transport as provided in Article 121 of this Law shall have the right to	1. Amend Articles 21 and 121 of Law No. 05/L-064 on Driving License so that the Authorization for holding trainings and seminars for driving instructors is renamed to Permit for holding trainings and seminars for driving instructors.	The authorization to hold trainings and seminars for driving instructor meets all the criteria of the Permit as defined by Article 3, paragraph 1.8, and Article 8 of Law No. 04/L-202 on Permit and License System. Furthermore, since the applicant has already proved that he meets the criteria for obtaining the authorization, the re-authorization procedure should be

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					<p>train drivers who want to become instructors.</p> <p>2. Law No. 05/L-064 on Driving License and Administrative Instruction No. 21/2017 on holding trainings and seminars in the field of driving license do not define in any Article the validity of this authorization in five (5) years, but in practice this authorization is given with such validity period.</p> <p>3. The appeal procedure is not in accordance with the LGAP.</p> <p>4. When applying for this authorization, the applicant pays a fee of</p>	<p>2. Amend Articles 21 and 121 of Law No. 05/L-064 on Driving License so that the Authorization for holding trainings and seminars for driving instructor is determined as permanent validity.</p> <p>3. To regulate The appeal procedure in accordance with the LGAP.</p> <p>4. Propose to the Ministry that the fee of EUR 500 paid for obtaining this authorization be calculated within the cost of obtaining this authorization, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>abolished. For this purpose, control mechanisms should be developed that ensure that the authorized entity continues to meet the legal criteria for the license it holds. In this form, the administrative and financial burden is lifted from both relevant institutional officials and applicants, namely the fee of EUR 500 is abolished.</p> <p>4. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500 reflects the costs incurred by the authority during the licensing process.</p>

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					EUR 500.		
Ministry of Environment, Spatial Planning and Infrastructure	DTT1	Licence D for third-party and rented transport abroad (international)	Permit	Ministry of Infrastructure, Department of Road Transport	<p>1. Law No. 04/L-179 on Road Transport stipulates in Article 42 License D for third-party and rented transport abroad.</p> <p>2. Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods and Administrative Instruction No. 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods, determines in Article 10 an</p>	<p>1. Amend Law No. 04/L-179 on Road Transport which in Article 42 provides for License D for third-party and rented transport abroad, so that it provides for Permit D transport for third-party and rented transport abroad instead.</p> <p>2. Amend Article 10 of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods, namely Administrative Instruction No. 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law.</p> <p>2. Abolition of the requirement to pay upon application is made in accordance with Article 18 of Law No. 04/L-202 on Permit and License System.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis</p>

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					<p>application fee of EUR 20.</p> <p>3. When applying for this permit, the applicant pays the fee of EUR 500.</p>	<p>Transport Operators of Goods, to abolish the fee of EUR 20.</p> <p>3. Propose to the Ministry that the fee of EUR 500 paid for obtaining this license be calculated within the cost of obtaining this license, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>whether the fee of EUR 500 reflects the costs incurred by the authority during the licensing process.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DTT2	Licence for transport of dangerous goods	Permit	Ministry of Infrastructure, Department of Road Transport	<p>1. Law No. 04/L-183 on Land Transport of Dangerous Goods stipulates in Article 7 the License for Transportation of Dangerous Goods.</p> <p>2. Administrative Instruction No. 12/2013 on the criteria and</p>	<p>1. Amend Law No. 04/L-183 on Land Transport of Dangerous Goods Article 7 which foresees the License for Transport of Dangerous Goods, to foresee instead the Permit for Transport of Dangerous Goods.</p> <p>2. Amend Article 7</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law.</p> <p>2. Abolition of the requirement to pay upon application is made in accordance with Article 18 of</p>

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					<p>procedure for issuance, cancellation and revocation of license for land transport of dangerous goods stipulates in Article 7 that the road transport operator of dangerous goods applying for a license must pay the fee of EUR 50 upon application.</p> <p>3. When applying for this license, the applicant pays the fee of EUR 300</p>	<p>of Administrative Instruction No. 12/2013 on Criteria and Procedures for Issuance, Suspension and Revocation of the License for Land Transport of Dangerous Goods, which provides that the road transport operator of dangerous goods applying for a license must pay a fee of EUR 50 upon application, so that this requirement is abolished.</p> <p>3. Propose to the Ministry that the fee of EUR 300 paid for obtaining this license be calculated within the cost of obtaining this license, to ensure compliance with Article 18 of the Law on Permits and Licenses. This calculation can be</p>	<p>Law No. 04/L-202 on Permit and License System.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 300 reflects the costs incurred by the authority during the licensing process.</p>

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						done by the project.	
Ministry of Environment, Spatial Planning and Infrastructure	DTT3	Licence C for transport of goods for own use in international road transport	Permit	Ministry of Infrastructure, Department of Road Transport	<p>1. Law No. 04/L-183 on Land Transport of Dangerous Goods stipulates in Article 7 the License C for transport of goods for own use in international road transport.</p> <p>2. Administrative Instruction No. (MI) 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods stipulates in Article 7 that the applicant must pay a fee of EUR 10 upon application.</p>	<p>1. Amend Law No. 04/L-183 on Land Transport of Dangerous Goods Article 7, which foresees License C for transport of goods for own needs in international road transport, in order to foresee instead Permit C for transport of goods for own use in international road transport</p> <p>2. Amend Article 7 of Administrative Instruction No. (MI) 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods, to abolish the</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law.</p> <p>2. Abolition of the requirement to pay upon application is made in accordance with Article 18 of Law No. 04/L-202 on Permit and License System.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis</p>

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					<p>3. When applying for this license, the applicant pays the fee of EUR 200.</p>	<p>requirement that the applicant pay the fee of EUR 10 upon application.</p> <p>3. Propose to the Ministry that the fee of EUR 200 paid for obtaining this license be calculated within the cost of obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>whether the fee of EUR 200 reflects the costs incurred by the authority during the licensing process.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DTT4	Licence for terminals	Permit	Ministry of Infrastructure, Department of Road Transport	<p>1. Law No. 04/L-183 on Land Transport of Dangerous Goods foresees in Article 7 the license for terminals.</p> <p>2. Administrative Instruction No. 08/2015 on Licensing of Terminals for Goods foresees</p>	<p>1. Amend Law No. 04/L-183 on Land Transport of Dangerous Goods, which foresees in Article 7 a License for terminals to foresee instead a Permit for terminals.</p> <p>2. Amend Article 8 of Administrative Instruction No. 08/2015 on</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law.</p> <p>2. Abolition of the requirement to pay upon application is made in accordance with Article 18 of</p>

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					<p>in Article 8 the obligation to pay EUR 100 when applying for a license.</p> <p>3. When applying for this license, the applicant pays the fee of EUR 2,000</p>	<p>Licensing of Terminals for Goods, to abolish the obligation to pay EUR 100 when applying for a license.</p> <p>3. Propose to the Ministry that the fee of EUR 2,000 paid for obtaining this license be calculated within the cost for obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	<p>Law No. 04/L-202 on Permit and License System.</p> <p>The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 2,000 reflects the costs incurred by the authority during the licensing process.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DTT5	Certificate of trucks for international transport of goods for own use		Ministry of Infrastructure, Department of Road Transport	1. Article 4 of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods stipulates the obligation to be equipped with a vehicle certificate, as a	1. Amend Article 4 of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods stipulates the obligation to be equipped with a vehicle certificate, as a document	<p>This certificate should not be included in the register of permits and licenses as it is neither of them.</p> <p>This certificate is necessary only for additional trucks used by the company which were not used to fulfil the criterion for obtaining the permit (Directive/Regulation on access to profession</p>

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					<p>document issued by the competent body for each vehicle registered in the name of the road transport operator of goods licensed by the Ministry.</p> <p>2. Administrative Instruction No. 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods stipulates in Article 10 the obligation to pay the fee of EUR 20 to apply for this certificate.</p>	<p>issued by the competent body. This requirement should only apply to trucks which were no certified when the permit was obtained.</p> <p>2. Amend Article 10 of Administrative Instruction No. 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods, in order to abolish the obligation to pay the fee of EUR 20 when applying for this certificate.</p>	<p>1071/2009; 1072/2009 and 1073/2009 on international transport of passengers and goods).</p> <p>2. Abolition of this certificate would alleviate the administrative burden on businesses by removing the payment of EUR 20 due for each bus every 5 years.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DTT6	Certificate of trucks for international transport of third-party, rented and paid transport of goods		Ministry of Infrastructure, Department of Road Transport	<p>1. Article 4 of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of</p>	<p>1. Amend Article 4 of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods</p>	<p>1. This certificate should not be included in the register of permits and licenses as it is neither of them.</p> <p>2. This certificate is completely unnecessary. The</p>

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					<p>Goods stipulates the obligation to be equipped with a vehicle certificate, as a document issued by the competent body for each vehicle registered in the name of the road transport operator of goods licensed by the Ministry.</p> <p>2. Administrative Instruction No. 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods stipulates in Article 10 the obligation to pay the fee of EUR 20 to apply for this certificate.</p>	<p>stipulates the obligation to be equipped with a vehicle certificate, as a document issued by the competent body. This requirement should only apply to trucks which were no certified when the permit was obtained.</p> <p>2. Amend Article 10 of Administrative Instruction No. 02/2015 on Amendment and Supplementation of Administrative Instruction No. 07/2013 on Licensing of Road Transport Operators of Goods, in order to abolish the obligation to pay the fee of EUR 20 when applying for this certificate.</p>	<p>vehicles are already registered and can be easily identified in the Ministry database. Such a certificate would make sense if a distinction were made between transport conditions. Removing the certificate would greatly ease the administrative burden on businesses thus eliminating unnecessary payment. Furthermore, the same legal basis is used by officials for the issuance of Certificates of trucks for international third-party, rented and paid transport of goods necessary only for additional trucks used by the company which were not used to fulfil the criterion for obtaining the permit (Directive/Regulation on access to profession 1071/2009; 1072/2009 and 1073/2009 on international transport of passengers and goods).</p> <p>3. Abolition of this certificate would alleviate the administrative burden on businesses by removing the payment of EUR 20 due for</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							each bus every 5 years.
Ministry of Environment, Spatial Planning and Infrastructure	DTT7	License for free transport, access and transit crossing through the territory of Kosovo, etc.	Permit	Ministry of Infrastructure, Department of Road Transport	<p>1. Administrative Instruction No. 06/2015 for issuance of licenses for carrying out regular international road transport of passengers for accessing and transit crossing through the territory of Kosovo stipulates in Articles 16 and 24 the obligation to pay a fee of EUR 50 when applying for a permit.</p> <p>2. Article 9 of Administrative Instruction No. 2/2009 on issuing permits to perform the international</p>	<p>1. Amend Administrative Instruction No. 06/2015 for issuance of licenses for carrying out regular international road transport of passengers for accessing and transit crossing through the territory of Kosovo, so as to abolish the obligation to pay the fee of EUR 50.</p> <p>2. Amend Article 9 of Administrative Instruction No. 2/2009 on issuing permits to perform the international road transport of passengers, access and transit through the territory of Kosovo so that the applicant is not required to submit</p>	<p>1. Abolition of the requirement to pay upon application is made in accordance with Article 18 of Law No. 04/L-202 on Permit and License System.</p> <p>2. Removal of the requirement to submit certified documents upon application such as: License A, B or D for passenger transport issued by MESPI and (ii) Proof of bus capacity, certified by MESPI (logbook, valid technical control, bus security as well as the certificate according to license A, B, D and the bus certificate is recommended because these documents are issued by the Ministry itself. The Ministry must have them available in a database.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>road transport of passengers, access and transit through the territory of Kosovo stipulates that the applicant must submit the following documents:</p> <p>(i) License A, B or D for passenger transport issued by MESPI and (ii) Certificate of capacity of buses, certified by MESPI (logbook, valid technical control, bus security and certificate under license A, B, D and bus certificate).</p> <p>3. When applying for this permit, the applicant pays the fee of EUR 100 - 500</p>	<p>the following documents:</p> <p>(i) License A, B or D for passenger transport issued by MESPI and (ii) Certificate of capacity of buses, certified by MESPI (logbook, valid technical control, bus security and certificate under license A, B, D and the bus certificate</p> <p>3. Propose to the Ministry that the fee of EUR 100 - 500 paid for obtaining this permit be calculated within the cost of obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project</p>	<p>cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 100-500 reflects the costs incurred by the authority during the licensing process.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry of Environment, Spatial Planning and Infrastructure	DTT8	License for free international road transport of passengers	Permit	Ministry of Infrastructure, Department of Road Transport	<p>1. Administrative Instruction No. 06/2015 on the issuance of permits for the performance of regular international road transport of passengers, access and transit through the territory of Kosovo, in Article 16, envisages the obligation to pay a fee of EUR 50 when applying for a permit.</p> <p>2. Administrative Instruction No. 06/2015 on the issuance of permits for transport in the international road traffic of passengers, access and transit through the territory of Kosovo requires the submission</p>	<p>1. Amend Administrative Instruction No. 06/2015 on the issuance of permits for the performance of regular international road transport of passengers, access and transit through the territory of Kosovo, so as to abolish the obligation to pay the fee of EUR 50 when applying.</p> <p>2. Amend Administrative Instruction No. 06/2015 on the issuance of permits for transport in international road traffic of passengers, access and transit through the territory of Kosovo to abolish the requirement for submitting the following</p>	<p>1. Abolition of the requirement to pay a fee upon application is made in accordance with Article 18 of Law 04/L-202 on Permit and License System. Abolition of the requirement to submit notarized documents upon application such as: License A, B, or D; The bus logbook, valid technical control, bus insurance and certificate according to licenses A, B, D, is recommended because these documents are issued by the Ministry itself. The Ministry must have them available in a database.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 100 reflects the costs incurred by the authority during the</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>of the following documents to apply: License A, B, or D; Bus logbook, valid technical control, bus insurance and certificate according to license A, B, D.</p> <p>3. When applying for this permit, the applicant pays a fee of EUR 100.</p>	<p>documents when applying: License A, B or D; Bus logbook, valid technical control, bus insurance and certificate according to license A, B and D.</p> <p>3. Propose to the Ministry that the fee of EUR 100 paid for obtaining this permit be calculated within the cost of obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	licensing procedure.
Ministry of Environment, Spatial Planning and Infrastructure	DTT9	Permit for regular international road transport of passengers to local transport operators	Permit	Ministry of Infrastructure, Department of Road Transport	1. Administrative Instruction No. 06/2015 on the issuance of permits for the performance of regular international road transport of passengers,	1. Amend Administrative Instruction No. 06/2015 on the issuance of permits for the performance of regular international road transport of	<p>1. Abolition of the requirement to pay a fee upon application is made in accordance with Article 18 of Law 04/L-202 on Permit and License System.</p> <p>2. Abolition of the requirement to submit notarized documents upon</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>access and transit through the territory of Kosovo stipulates in Article 16 the obligation to pay a fee of EUR 100 when applying for a permit.</p> <p>2. Administrative Instruction No. 06/2015 for issuance of licenses for carrying out regular international road transport of passengers for accessing and transit crossing through the territory of Kosovo requires the submission of the following documents to apply: License B or D for passenger transport.</p> <p>3. When</p>	<p>passengers, access and transit through the territory of Kosovo, so as to abolish the obligation to pay the fee of EUR 50 when applying.</p> <p>2. Amend Administrative Instruction No. 06/2015 for issuance of licenses for carrying out regular international road transport of passengers for accessing and transit crossing through the territory of Kosovo, which requires the submission of the following documents to apply: License B or D for passenger transport.</p> <p>3. Propose to the Ministry that the fee of EUR 50 - 100 paid for obtaining</p>	<p>application such as: License A, B, or D is recommended because these documents are issued by the Ministry itself. The Ministry must have them available in a database.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 50-100 reflects the costs incurred by the authority during the licensing procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					applying for this permit, the applicant pays the fee of EUR 50 – 100.	this permit be calculated within the cost of obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project	
Ministry of Environment, Spatial Planning and Infrastructure	DTT10	Permit for special transport of passengers	Permit	Ministry of Infrastructure, Department of Land Transport	<p>1. Administrative Instruction No. 09/2013 on the routes network and timetables of interurban passenger transport by bus and AI No. 06/2016 on amendment thereof stipulates in Article 15.2 the obligation for payment of EUR 50 when applying.</p> <p>2. Administrative Instruction No. 09/2013 on the routes network and timetables of interurban</p>	<p>1. Amend Administrative Instruction No. 09/2013 on the routes network and timetables of interurban passenger transport by bus and AI No. 06/2016 on amendment thereof, Article 15.2, and abolish the obligation to pay the fee of EUR 50 when applying.</p> <p>2. Amend Administrative Instruction No. 09/2013 on the routes network and timetables of interurban passenger</p>	<p>1. Abolition of the requirement to pay a fee upon application is made in accordance with Article 18 of Law 04/L-202 on Permit and License System.</p> <p>2. Abolition of the requirement to submit notarized documents upon application such as: License C or D is recommended because these documents are issued by the Ministry itself. The Ministry must have them available in a database.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>passenger transport by bus and AI No. 06/2016 on amendment thereof stipulate that License C or D for passenger transport must be submitted to apply.</p> <p>3. When applying for this permit, the applicant pays the fee of EUR 200 - 600</p>	<p>transport by bus and AI No. 06/2016 on amendment thereof, in order to abolish the requirement to submit License C or D for passenger transport upon application.</p> <p>3. Propose to the Ministry that the fee of EUR 200-600 paid for obtaining this permit be calculated within the cost for obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project</p>	<p>permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 200-600 reflects the costs incurred by the authority during the licensing procedure.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DTT11	Authorization for own use	Notice	Ministry of Infrastructure, Department of Land Transport	<p>1. Law No. 04/L-179 on Road Transport stipulates in Article 35 that this authorization should be obtained by</p>	<p>1. Change the name of this permission from Authorization to Notice.</p> <p>2. Abolish the requirement to pay the fee of EUR 50 upon application.</p>	<p>1. This authorization meets all the requirements to be classified as a Notice according to Article 6 of the Law on Permit and License System.</p> <p>2. Abolition of the payment upon application is</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>companies for carrying out the transport of their own employees.</p> <p>2. To obtain this authorization, the applicant pays a fee of EUR 50.</p>		<p>recommended in accordance with Article 18 of Law No. 04/L-202 on Permit and License System.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DTT12	<p>1. License A - for free transport inside and outside Kosovo.</p> <p>2. License B – for free na dregular international road transport of passengers by bus</p>	Permit	Ministry of Infrastructure, Department of Land Transport	<p>1. License A applies when a company wants to provide transportation for tourists To apply for this license, the applicant should submit the following documents: (i) Business registration certificate in Kosovo for the activity of road transport of passengers and fiscal number certificate; (ii) proof of Professional Competence</p>	<p>1. Amend Law No. 04/L-179 on Road Transport, Article 7, which foresees the license as a necessity for exercising the activity of operators, so that the need for obtaining a permit and not a license is foreseen.</p> <p>2. Amend Administrative Instruction No. 07/2015 2015 on the licensing of road transport operators of passengers by bus to provide for obtaining a permit</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law. The two licenses should be merged as they cover the provision of the same service, but at different periods. In addition, this proposal was made by the Ministry officials.</p> <p>2. Abolition of the requirement to pay upon application is made in accordance with Article 18 of Law 04/L-202 on Permit and License System.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>(CPC) and of trained and certified professional capacity.</p> <p>2. License B is applied when the company wishes to provide services not only on a seasonal basis, but in regular and continuous manner.</p> <p>3. Article 8 of Administrative Inatruccion No. 07/2015 of road transport operators of passengers by bus stipulates the fee of EUR 50 to be paid when applying for each of the licenses.</p> <p>4. Administrative Inatruccion No. 07/2015 of road transport</p>	<p>instead of a license, and to merge License A and License B, so as to require only obtaining a Permit for the provision of these services. As exceptions to this general rule would be situations when there are bilateral agreements between countries.</p> <p>3. Amend Administrative Instruction No. 07/2015 on the licensing of road transport operators of passengers by bus, more precisely paragraph 1.1 of Article 8 in order to abolish the obligation for the applicant to pay the fee of EUR 50 when applying.</p> <p>4. Amend Administrative Instruction No. 07/2015 on</p>	<p>3. Abolition of the requirement to submit the following notarized documents when applying: proof of Professional Competence (CPC) and of trained and certified professional capacity is recommended because these documents are issued by the Ministry itself. The Ministry must have them available in a database.</p> <p>4. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 200 reflects the costs incurred by the authority during the licensing procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>operators of passengers by bus stipulates that when applying for licensing, the applicant should submit proof of Professional Competence (CPC) and of trained and certified professional capacity.</p> <p>5. When applying for license A, the applicant pays the fee of EUR 300, while the application fee for license B is EUR 500</p>	<p>licensing of operators of road passenger transport by bus so as to abolish the obligation of the applicant to submit proof of Professional Competence (CPC) and of trained and certified professional capacity.</p> <p>5. Propose to the Ministry that the fee of EUR 300 and EUR 500 paid for obtaining these licenses be calculated within the cost of obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project.</p>	
Ministry of Environment, Spatial Planning and	DTT13	1. License C - means the exercise of the activity of free and regular local road	Permit	Ministry of Infrastructure, Department of Land Transport	1. Law No. 04/L-179 on Road Transport stipulates in	1. Amend Law No. 04/L-179 on Road Transport, Article 7, which foresees the	1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Infrastructure		transport of passengers by bus 2. License D - free and regular local and international road transport of passengers by bus			<p>Article 7 the license as a necessity for exercising the activity of operators.</p> <p>2. License C is applied when the company wishes to provide free and regular local road transport of passengers by bus, while license D is applied when the company wishes to provide free and regular local and international road transport of passengers by bus</p> <p>3. Administrative Instruction No. 07/2015 on the licensing of road transport operators of passengers by bus, in</p>	<p>license as a necessity for exercising the activity of operators, so that the need for obtaining a permit and not a license is foreseen. As exceptions to this general rule would be situations when there are bilateral agreements between countries.</p> <p>2. Amend Administrative Instruction No. 07/2015 on the licensing of road transport operators of passengers by bus, more precisely paragraph 1.1 of Article 8 in order to abolish the obligation for the applicant to pay the fee of EUR 50 when applying, and to merge licensed C and D so that a single permit is required for the</p>	<p>persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law. The two licenses should be merged as they cover the provision of the same service. In addition, this proposal was made by the Ministry officials.</p> <p>2. Abolition of the requirement to pay upon application is made in accordance with Article 18 of Law 04/L-202 on Permit and License System.</p> <p>3. Abolition of the requirement to submit the following notarized documents when applying: proof of Professional Competence (CPC) and of trained and certified professional capacity is recommended because these documents are issued by the Ministry itself. The Ministry must have them available in a database.</p> <p>4. The fee that a competent authority may charge for a</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>paragraph 1.1 of Article 8, obliges the applicant to pay the fee of EUR 50 when applying.</p> <p>4. Administrative Instruction No. 07/2015 on licensing of operators of road passenger transport by bus provides that in the case of licensing, the applicant must submit proof of Professional Competence CPC possesses trained and certified professional capacity for both licenses.</p> <p>5. When applying for this license, the applicant pays the fee of EUR 200, while the application fee</p>	<p>provision of these services.</p> <p>3. Amend Administrative Instruction No. 07/2015 on licensing of operators of road passenger transport by bus so as to abolish the obligation of the applicant to submit proof of Professional Competence (CPC) and of trained and certified professional capacity.</p> <p>4. Propose to the Ministry that the fees of EUR 200 and EUR 1,000 paid for obtaining these licenses be calculated within the cost of obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This</p>	<p>permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 200 and EUR 1,000 reflect the costs incurred by the authority during the licensing procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					of rlicense D is EUR 1,000.	calculation can be done by the project.	
Ministry of Environment, Spatial Planning and Infrastructure	DTT14	License according to categories A, B, C and D for bus stations	Permit	Ministry of Infrastructure, Department of Land Transport	<p>1. Law No.04/L-179 on Road Transport stipulates in Article 37 the license according to categories A, B, C and D for bus stations</p> <p>2. Administrative Instruction No. 08/2013 on licensing of bus stations in Article 6 provides that the license for bus station is issued on the basis of categories and not a general license and the same has a validity of five (5) years. 2. Al No. 08/2013, in Article 5, provides the obligation to pay the amount of</p>	<p>1. Amend Law No. 04/L-179 on Road Transport Article 37, which foresees the license as a necessity for exercising the activity of operators, so that the need for obtaining a permit and not a license is foreseen.</p> <p>2. Amend Article 6 of Administrative Instruction No. 08/2013 so as to allow obtaining a license for two or more categories with one procedure and to determine the validity of the license to be permanent and not five (5) years. In case the subject is initially licensed only for one category, at the</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this law.</p> <p>2. In case of merging the licensing procedure into a single one, the applicant is relieved of the burden of providing the same documents for each category. In case the applicant is licensed only for one category and in the future he wants to be licensed for other categories, he offers only the evidence of fulfillment of the conditions provided by law and does not duplicate documents that are already found in the Ministry and the existence of a category of the license proves their existence. Such a fusion of</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>EUR 100 when applying.</p> <p>3. When applying for this license, the applicant pays the amount of EUR 500 to 3,000</p>	<p>moment he requests the licensing for other categories, it should suffice only to add the necessary documents and not to start the procedure from the beginning.</p> <p>3. Amend Administrative Instruction No. 08/2013 on the licensing of bus stations, in Article 5, in order to abolish the obligation to pay the amount of EUR 100 when applying.</p> <p>4. Propose to the Ministry that the fee of EUR 500 - 3,000 paid for obtaining this license be calculated within the cost of obtaining it, to ensure compliance with Article 18 of</p>	<p>the procedure, in addition to easing the administrative burden of an applicant, also facilitates the work of the responsible officials. Furthermore, since the subject in the licensing case has already proved that it meets the licensing criteria, the re-licensing procedure should be completely abolished. For the same, supervisory mechanisms should be developed to ensure that the licensed entity continues to meet the legal criteria for the license it holds. In this form, the administrative and financial burden is eased to the relevant entity and institutional officials. Abolition of the requirement to pay upon application is made in accordance with Article 18 of Law 04/L-202 on Permit and License System.</p> <p>3. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						the Law on Licenses. This calculation can be done by the project	in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the fee of EUR 500-3,000 reflects the costs incurred by the authority during the licensing procedure.
Ministry of Environment, Spatial Planning and Infrastructure	DTT15	Certificate for buses		Ministry of Infrastructure, Department of Land Transport	<p>1. Article 8 of Law No. 04/L-179 on Road Transport provides the obligation to obtain a bus certificate for all buses after the company is licensed and the buses are registered.</p> <p>2. Administrative Instruction No. 07/2015 on the licensing of road transport operators of passengers by bus, in Article 11, paragraph 5.1, provides the</p>	<p>1. Amend Article 8 of Law No. 04/L-179 on Road Transport which stipulates the obligation to obtain a bus certificate for all buses after the company is licensed and the buses are registered. This requirement should only apply to buses which were no certified when the permit was obtained.</p> <p>2. Amend Administrative Instruction No. 07/2015 on licensing of road transport operators</p>	<p>1. This certificate should not be included in the register of permits and licenses as it is neither of them.</p> <p>2. This certificate is completely unnecessary. The vehicles are already registered and can be easily identified in the Ministry database. Such a certificate would make sense if a distinction were made between transport conditions. Removing the certificate would greatly ease the administrative burden on businesses thus eliminating unnecessary payment. Furthermore, the same legal basis is used by officials for the issuance of Certificates of trucks for international third-party,</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					obligation to pay the fee of EUR 50 when applying for a certificate.	of passengers by bus, in Article 11, paragraph 5.1, so as to abolish the obligation to pay the fee of EUR 50 when applying for a certificate.	rented and paid transport of goods necessary only for additional trucks used by the company which were not used to fulfil the criterion for obtaining the permit (Directive/Regulation on access to profession 1071/2009; 1072/2009 and 1073/2009 on international transport of passengers and goods). 3. Abolition of this certificate would alleviate the administrative burden on businesses by removing the payment of EUR 20 due for each bus every 5 years.
Ministry of Environment, Spatial Planning and Infrastructure	DTT16	Permit for extraordinary transport of goods	Permit	Ministry of Infrastructure, Department of Road Management	1. Administrative Instruction No. 04/2014 on Extraordinary Transport, in Article 9, provides for the validity of the permit for a period of one (1) month. 2. In paragraph 1.1 of Article 7 of Administrative Instruction No.	1. Amend Article 9 of Administrative Instruction No. 04/2014 on Extraordinary Transport, so as to provide for the validity of the permit for extraordinary transport of goods for a period of one (1) year and not for one (1) month. 2. Amend paragraph	1. The short time provided for the validity of this permit, i.e., one (1) month, is considered to be a very great burden for the operator, but also for the responsible official. In order to address the risk, pollution and damage caused by this type of transport, it is proposed to increase the amount paid for this permit and at the same time to increase its validity time. 2. Abolition of the

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>04/2014 for Extraordinary Transport, there is an obligation to pay a fee of EUR 20 when applying for this permit.</p> <p>3. The appeal procedure is not regulated according to the LGAP.</p>	<p>1.1 of Article 7 of Administrative Instruction No. 04/2014 for Extraordinary Transport, so that the fee of EUR 20 is not required for obtaining a permit.</p> <p>3. Regulate the appeal procedure according to the LGAP.</p>	<p>requirement to pay upon application is made in accordance with Article 18 of Law 04/L-202 on Permit and License System.</p>
Ministry of Environment, Spatial Planning and Infrastructure	DA7	Certificate for driving license trainers	Professional license	Ministry of Infrastructure, Department of Vehicles	<p>1. Article 112.3 of Law No. 05/L-064 on Driving License provides the Certificate for trainer in the field of driving license.</p> <p>2. Article 23 of the Administrative Instruction (MI) No. 11/2017 for Trainers in the Field of Driving License provides for obtaining this certificate.</p> <p>3. Decision of</p>	<p>1. Amend Article 112.3 of Law No. 05/L-064 on Driving License which stipulates the Certificate for trainer in the field of driving license, so as to stipulate the Permit of driving license trainer instead.</p> <p>2. Amend Decision of the Minister No. 8325 dated 02.11.2017, which is based on Article 25 of Administrative Instruction No.</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law.</p> <p>2. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>the Minister No. 8325 dated 02.11.2017 which is based on Article 25 Administrative Instruction No. 11/2017 for Trainers in the Field of Driving License determines the following fees for this certificate:</p> <p>In order to apply for the written part of the qualifying exam/re-examination for trainer in the field of driving license – EUR 50</p> <p>In order to apply for the professional exam-re-examination for a trainer in the field of driving license:</p> <p>- Written part – EUR 50</p>	<p>11/2017 for Trainers in the Field of Driving License so as to abolish the requirement to pay a fee of EUR 200 for obtaining the certificate.</p> <p>3. Propose to the Ministry that the fee of EUR 1,500 paid for the performance of this training be calculated within the cost for obtaining it, to ensure compliance with Article 18 of the Law on Licenses. This calculation can be done by the project</p>	<p>assist with this calculation, as well as with the analysis whether the fee of EUR 1,630 reflects the costs incurred by the authority during the licensing procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>- Oral part – EUR 30</p> <p>- Practical part - EUR 100</p> <p>Issuance of the certificate - EUR 200</p> <p>Participation in the basic training for trainers in the field of driving license - EUR 1,150</p> <p>For participation in the training for certified trainer in the field of driving license EUR 50.</p>		
Ministry of Environment, Spatial Planning and Infrastructure	DA8	License for technical control of vehicles	Permit	Ministry of Infrastructure, Department of Vehicles	<p>1. Law No. 05/L-132 on Vehicles in Articles 88 and 91 provides for the need to obtain a License for the operator.</p> <p>2. Article 12 of Administrative Instruction (MI) No.01/2018 on Technical Inspection of Vehicles stipulates a fee</p>	<p>1. Amend Law No. 05/L-132 on Vehicles in Articles 88 and 91 which provide for the need to obtain a License for the operator, so as to determine the need for obtaining a Permit instead of a License.</p> <p>2. Propose to the Ministry that the fee of EUR 3,000</p>	<p>1. Based on Law No. 04/L-202 on Permit and License System, the professional license is issued to natural persons, while the permit is issued to legal persons as in this case. Therefore the proposed amendment is based on Articles 8 and 9 of this Law.</p> <p>2. The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>of EUR 3000 for the line of technical inspection of vehicles up to 3.5 t; a fee of EUR 2000, for the line of technical control of vehicles over 3.5t; and a fee of EUR 300 for the line of technical control of motorcycles</p>	<p>for the line of technical control of vehicles up to 3.5 t; fee of EUR 2,000 for the line of technical control of vehicles over 3.5t; the fee of EUR 300 for the line of technical control of motorcycles that is paid for obtaining this license to be calculated within the cost of obtaining it, to ensure that it is accordance with Article 18 of the Law on Licenses. This calculation can be done by the project</p>	<p>competent authority incurs in administering the permission (Article 18 of the Law on Permit and License System). The project can assist with this calculation, as well as with the analysis whether the total amount reflects the costs incurred by the authority during the licensing process.</p>

Simplification of permits and licenses at the Ministry of Health

In the process of simplifying permits and licenses at the Ministry of Health and harmonizing them with Law 04/L-202 on Permit and License System, a total of 55 permits and licenses were analyzed. This draft report aims to identify, analyze and provide recommendations for the simplification of permits and licenses administered by the Ministry of Health (MoH), the Kosovo Medicines Agency (KMA), and the Chambers of Healthcare Professionals, namely the Kosovo Doctors Chamber (OMK), Chamber of Physiotherapists of Kosovo (OFK), Chamber of Dentists of Kosovo (OMK), Kosovo Chamber of Pharmacists (OFK), and Kosovo Chamber of Nurses (KNC).

The process of inventory and analysis of permits and licenses, completed during the period September - November 2021 has been done in a transparent and comprehensive manner. Initially, all permits and licenses administered by the MoH, KMA, and the Chambers of Health Professionals were identified. At the same time, the legal basis was identified, namely the laws and sub-legal acts, which regulate these permits and licenses. After their identification, in order to understand how they are implemented in practice, numerous meetings and discussions were held with officials of the Ministry and related agencies. During these meetings, relevant forms for all identified permits and licenses were completed, and together with the project team, the collected information was checked. In addition, two focus groups were conducted with representatives of the private sector as well as healthcare professionals to see the impact of permits on their work. In the last phase, based on the information gathered and the legal and economic analysis, recommendations were prepared for the simplification of each permit and license, summarized in this draft report.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Chamber of Physiotherapists of Kosovo	OFK1-A	Licensing of physiotherapists	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure is missing.</p> <p>4. Inappropriate and restricted payment method.</p> <p>5. This Chamber delivers almost all licensing services, as well as other services electronically through its website https://oftk-ks.org/ which is sufficiently user friendly.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation No. 01/2020 on Procedures and Criteria for Membership in OFK, to require only information, to be submitted ex officio, without needing to submit documents such as: Copy of ID card, Notarized Certificate of professional exam or specialist exam, Membership identification card (this card is issued free of charge).</p> <p>3. Amend Regulation No. 01/2020 on Procedures and Criteria for Membership in OFK, which establishes the right to appeal, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision No. 01/2020 on Administrative Fees for OFK services so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>6. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p>	<p>Amendment of law No. 04/L-150 on Chambers of Healthcare Professionals is needed to harmonize this Law with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be determined only by law.</p> <p>The amendment of Regulation No. 01/2020 on the Procedures and Criteria for Membership in OFK is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting the procedure ex officio according to the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation should be made to regulate the right to appeal procedure which is completely missing.</p> <p>Amendment of Decision No. 01/2020 on administrative fees for OFK services should be made to enable payment at the end to avoid frequency of and loss of time for payment, as well as to lift the restriction of only one form of payment proof accepted.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>7. In cases when the submission of some documents is necessary, not to request a notarized copy of them; e.g. 'Notarized certificate of professional exam or specialist exam' required. Notarization is not required as this document is issued by the Ministry of Health itself. This applies to all licenses issued by OFK.</p> <p>8. Fees for licensing (EUR 80) as well as for stamping (EUR 20) are high and may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit). It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).</p>	The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.
Chamber of Physiotherapists of Kosovo	OFK1-B	Relicensing of physiotherapists	License	Commission for Continuing Professional Education (CCPE); License is signed by the Chair of the Licensing Commission and the Chair of the Chamber	Same as license OFK1-A	<p>1. The OFK1-B license should be issued for an indefinite term; The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</p> <p>2. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process.</p> <p>3. OFK1-A license does not need to be</p>	There is no need to follow the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-2020 on Permit and License System).

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained.</p> <p>4. Amend Regulation No. 01/2020 on Procedures and Criteria for Membership in OFK, which establishes the right to appeal, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint.</p> <p>5. These changes can be made by amending Regulation No. 01/20120 on Procedures and Criteria for Membership in OFK</p>	
Chamber of Physiotherapists of Kosovo	OFK2	License duplicate (copy of license)	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	This should not be included in the register as it is not a new license	<p>1. Require the submission of only a request with minimum data to make known the fact of loss and damage of the license.</p> <p>2. Other data are or should be in the register of licenses kept by the chamber.</p> <p>3. The duplicate copy should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p>	There is no need and no argument for implementing a procedure and convening the Licensing Commission to decide on an action as simple as the issuance of a duplicate copy, which can easily be ascertained and issued by the professional service of the Chamber.
Kosovo Doctors Chamber	OMK1-A	Licensing of Doctor of Medicine (general licensing)	License	Licensing Commission; License is signed by the Chair of the Commission and	1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation No. 01/2020 on</p>	Amendment of law No. 04/L-150 on Chambers of Healthcare Professionals is needed to harmonize this Law with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be determined only by law.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
(OMK)				the Chair of the Chamber	<p>revocation, but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure is missing.</p> <p>4. Inappropriate and restricted payment method.</p>	<p>Procedures and Criteria for Membership in OFK, to require only information, to be submitted ex officio, without needing to submit documents such as: Copy of ID card, Notarized Certificate of professional exam or specialist exam. Abolish the requirement for submitting a medical certificate (for retired doctors) because it shows the health condition but not the ability to practice medicine.</p> <p>3. Amend Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for submitting the appeal and deciding on the appeal.</p> <p>4. Amend Decision of OMK No. 02/2020 on Administrative Fees for OMK services so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p> <p>6. In cases when the submission of some documents is necessary, not to request a notarized copy of them; e.g. 'Notarized certificate of professional exam or specialist</p>	<p>The amendment of Regulation No. 01/2020 on the Procedures and Criteria for Membership in OFK is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting the procedure ex officio according to the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision No. 02/2020 on administrative fees for OMK services should be made to enable payment at the end to avoid frequency of and loss of time for payment, as well as to lift the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-202 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						exam' required. Notarization is not required as this document is issued by the Ministry of Health itself. This applies to all licenses issued by OMK.	
Kosovo Doctors Chamber (OMK)	OMK1-B	Licensing of Doctor of Medicine (general licensing)	License	Commission for Continuing Professional Education (CCPE); License is signed by the Chair of the Licensing Commission and the Chair of the Chamber	Same as OMK1-A license	<p>1. The OMK1-B license should be issued for an indefinite term; The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</p> <p>2. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process.</p> <p>3. OMK1-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained.</p> <p>4. Amend Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for submitting the appeal and deciding on the appeal.</p> <p>5. These changes can be made by amending Regulation No. 04/2020 on Registration,</p>	There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-202 on Permit and License System). Also, abolish the fee of EUR 40 for relicensing.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						Licensing, and Relicensing of Physicians.	
Kosovo Doctor's Chamber (OMK)	OMK2-A	Licensing of specialists and sub-specialists (specialist licensing)	License	Licensing Commission License is signed by the Chair of the Commission and the Chair of the Chamber	<ol style="list-style-type: none"> 1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit. 2. Some of the documents do not need to be requested from the party. 3. The appeal procedure is missing. 4. Inappropriate and restricted payment method. 	<ol style="list-style-type: none"> 1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers. 2. Amend Regulation No. 01/2020 on Procedures and Criteria for Membership in OFK, to require only information, to be submitted ex officio, without needing to submit documents such as: Copy of ID card, Notarized Certificate of professional exam or specialist exam. Abolish the requirement for submitting a medical certificate (for retired doctors) because it shows the health condition but not the ability to practice medicine. 3. Amend Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for submitting the appeal and deciding on the appeal. 4. Amend Decision of OMK No. 02/2020 on Administrative Fees for OMK services so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment. 5. The license should be signed by the Chair 	<p>Amendment of law No. 04/L-150 on Chambers of Healthcare Professionals is needed to harmonize this Law with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be determined only by law.</p> <p>The amendment of Regulation No. 01/2020 on the Procedures and Criteria for Membership in OFK is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting the procedure ex officio according to the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision No. 02/2020 on administrative fees for OMK services should be made to enable payment at the end to avoid frequency of and loss of time for payment, as well as to lift the restriction of only one form of payment proof accepted.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>of the Chamber or by a Chamber official authorized for this purpose.</p> <p>6. In cases when the submission of some documents is necessary, not to request a notarized copy of them; e.g. 'Notarized certificate of professional exam or specialist exam' required. Notarization is not required as this document is issued by the Ministry of Health itself. This applies to all licenses issued by OMK.</p>	The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-202 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.
Kosovo Doctors Chamber (OMK)	OMK2-B	Relicensing of specialists and sub-specialists (specialist licensing)	License	<p>Commission for Continuing Professional Education (CCPE);</p> <p>License is signed by the Chair of the Licensing Commission and the Chair of the Chamber</p>	Same as license OMK2-A	<p>1. The OMK1-A license should be issued for an indefinite term. 2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</p> <p>2. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process.</p> <p>3. OMK1-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained.</p> <p>4. Amend Regulation No. 04/2020 on</p>	There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-202 on Permit and License System).

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						Registration, Licensing, and Relicensing of Physicians which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for submitting the appeal and deciding on the appeal. 6. These changes can be made by amending Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians.	
Kosovo Doctors Chamber (OMK)	OMK3	Permit for bio-medical research (including permits for COVID)	License	Ethics Commission; License is signed by the Chair of the Commission Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians	1. Law No. 04/L-150 on Chambers of Healthcare Professionals does not regulate this type of permit anywhere. 2. Some of the documents do not need to be requested from the party. 3. The appeal procedure is missing. 4. Inappropriate and restricted payment method. 5. The deadline for issuing the license is missing.	1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers. 2. Amend Regulation No. 07/2020 on the Scope and Competencies of the Ethical Commission to require only information, to be submitted ex officio, without needing to submit documents such as: Copies of valid professional licenses of research participants. 3. Amend Regulation No. 07/2020 on the Scope and Competencies of the Ethical Commission which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for submitting the appeal and deciding on the appeal. 4. Amend Decision No. 02/2020 on Administrative Fees for OMK services so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of	Amendment of law No. 04/L-150 on Chambers of Healthcare Professionals is needed to harmonize this Law with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be determined only by law. The amendment of Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting the procedure ex officio according to the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems. Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>payment.</p> <p>5. Establish the deadline on procedure implementation and decision making for this type of license.</p> <p>6. Fees are very high (EUR 120-480) and may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) Fees should be determined based on the load of work and not according to the subject (natural person or legal person). It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).</p>	<p>Amendment of Decision No. 02/2020 on administrative fees for OMK services should be made to enable payment at the end to avoid frequency of and loss of time for payment, as well as to lift the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.</p>
Kosovo Doctors Chamber (OMK)	OMK4	License duplicate (license copy)	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	This should not be included in the register as it is not a new license	<ol style="list-style-type: none"> 1. Require only one request with minimum data to make known the fact of loss or damage of the license. 2. Other data are or should be in the register of licenses kept by the chamber. 3. The duplicate copy should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose. 	There is no need and no argument for implementing a procedure and convening the Licensing Commission to decide on an action as simple as the issuance of a duplicate copy, which can easily be ascertained and issued by the professional service of the Chamber.
Chamber of Pharm	OFK1-A	Licensing of pharmacist	License	Licensing Commission;	1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9,	1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the	Amendment of law No. 04/L-150 on Chambers of Healthcare Professionals is needed to harmonize this Law with Article 17, paragraph 1,

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry of Health of Kosovo (OFK)				License is signed by the Chair of the Commission and the Chair of the Chamber	<p>paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure in the case of licensing is missing, while for relicensing it is not complete.</p> <p>4. Inappropriate and restricted payment method.</p>	<p>chambers.</p> <p>2. Amend Regulation No. 08/2019 on Licensing and Relicensing of Pharmacists to require only information, to be submitted ex officio, without needing to submit documents such as: Copy of ID card, Notarized Certificate of professional exam or specialist exam, Membership identification card.</p> <p>3. Amend Regulation No. 08/2019 on Licensing and Relicensing of Pharmacists which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision No. 08/ on Administrative Fees for OFK services so that payment is made at the end of the procedure and is also made through e-banking, POS, etc.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p> <p>6. In cases when the submission of some documents is necessary, not to request a notarized copy of them; e.g. 'Notarized certificate of professional exam or specialist exam' required. Notarization is not required as this document is issued by the Ministry of</p>	<p>of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be determined only by law.</p> <p>Amendment of Regulation 08/2019 on Licensing and Relicensing of Pharmacists should be made to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting the procedure ex officio according to the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision No. 08/2019 on Administrative Fees for OFK services should be done to enable payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-202 on Permit and License System and should not exceed the amount required to cover the cost</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>Health itself. This applies to all licenses issued by OFK.</p> <p>8. Licensing fee of EUR 100 may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	that the competent authority incurs in administering the permission.
Chamber of Pharmacists of Kosovo (OFK)	OFK1-B	Relicensing of pharmacists	License	<p>Commission for Continuing Professional Education (CCPE);</p> <p>License is signed by the Chair of the Licensing Commission and the Chair of the Chamber</p>	Same as license OFK1-A	<p>1. The OFK1-license should be issued for an indefinite term; The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</p> <p>2. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process.</p> <p>3. OFK1-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained.</p>	There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-202 on Permit and License System).

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>4. Amend Regulation No. 08/2019 on Licensing and Relicensing of Pharmacists which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>5. These changes can be made by amending Regulation No. 08/2019 on Licensing and Relicensing of Pharmacists.</p> <p>6. Abolish the relicensing fee of EUR 100.</p>	
Chamber of Pharmacists of Kosovo (OFK)	OFK2	Permit for professional scientific research	Permit	Ethical Commission; Permit is signed by the Chair of the Ethical Commission	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals does not regulate this type of permit anywhere.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure is missing.</p> <p>4. Inappropriate and restricted payment method.</p> <p>5. The deadline for issuing the license is missing.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation No. 12/2020 on the Scope and Competencies of the Ethical Commission of OFK to require only information, to be submitted ex officio, without needing to submit documents such as: Copies of valid professional licenses of research participants.</p> <p>3. Amend Regulation No. 12/2020 on the Scope and Competencies of the Ethical Commission OFK which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision to supplement the</p>	<p>Amendment of law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of Regulation No. 12/2020 on the Scope and Competencies of the Ethical Commission of OFK is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a named document to a request, such as instead of requesting copies of valid professional licenses of research participants to request personal data is done in order to enable electronic communication, including interconnection of electronic systems</p> <p>Further, the amendment of the regulation</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>amendment Regulation No. 42 dated 08.08.2019 so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>5. Establish the deadline for procedure implementation and decision making for this type of license.</p> <p>6. The fees for this permit are very high (EUR 300-400) and may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) Fees should depend on the load of work for the provision of this service and not on the subject (natural or legal). It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).</p>	<p>should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of the decision to supplement the amendment of regulation No. 42 dated 08.08.2019 should be made to enable the payment at the end to avoid the frequency and loss of time for payment and on the other hand not to limit only one form of proof to prove the payment.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.</p>
Chamber of Pharmacists of Kosovo (OFK)	OFK3	License duplicate (license copy)	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	This license should not be included in the register as it is not a new license	<ol style="list-style-type: none"> 1. Require only one request with minimum data to make known the fact of loss or damage of the license. 2. Other data are or should be in the register of licenses kept by the chamber. 3. The duplicate copy should be signed by the Chair of the Chamber or by a Chamber 	There is no need and no argument for implementing a procedure and convening the Licensing Commission to decide on an action as simple as the issuance of a duplicate copy, which can easily be ascertained and issued by the professional service of the Chamber.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						official authorized for this purpose.	
Chamber of Dentists of Kosovo (OSK)	OSK1-A	General licensing (of doctors of stomatology)	Licence	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals Article 9 paragraph 1.3 regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure in the case of licensing is missing.</p> <p>4. Inappropriate and restricted payment method.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists to require only information, to be submitted ex officio, without needing to submit documents such as: copy of ID card, notarized certificate of professional exam or exam for specialists, membership card with which is evidenced by membership.</p> <p>3. Amend Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision on administrative fees for OSK services (12/2019) so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof proving payment.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p> <p>6. Licensing fee of EUR 100 may not be in</p>	<p>Amendment of law No. 04/L-150 on Chambers of Healthcare Professionals is needed to harmonize this Law with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be determined only by law.</p> <p>Amendment of Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists must be done to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation is needed to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision No. 08/2019 on Administrative Fees for OFK services should be done to enable payment in the end to avoid frequency of and loss of time for payment, as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-202</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).	on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.
Chamber of Dentists of Kosovo (OSK)	OSK1-B	General relicensing (of doctors of stomatology)	License	Commission for Continuing Professional Education (CCPE) valorizes the credit points, the Licensing Commission is responsible for approval; License is signed by the Chair of the Commission and the Chair of the Chamber	Same as license OSK1-A	<ol style="list-style-type: none"> The OSK1-B license should be issued for an indefinite term. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process. OsK1-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained. Amend Regulation No. 12/2019 on Registration, Licensing, and Relicensing of 	There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-202 on Permit and License System).

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>Dentists which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>6. These changes can be made by amending Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists.</p> <p>7. Abolish relicensing fee (EUR 100).</p>	
Chamber of Dentists of Kosovo (OSK)	OSK2-A	Specialist licensing (of specialists of stomatology)	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure in the case of licensing is missing.</p> <p>4. Inappropriate and restricted payment method.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists, to require only information, to be submitted ex officio, without needing to submit documents such as: copy of ID card, notarized certificate of professional exam or exam for specialists. Abolish the requirement for a medical certificate (for retired doctors) because it shows the health condition but not the ability to practice medicine.</p> <p>3. Amend Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p>	<p>Amendment of law No. 04/L-150 on Chambers of Healthcare Professionals is needed to harmonize this Law with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be determined only by law.</p> <p>Amendment of Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists must be done to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a named document to a request such as instead of a copy of the identity card requiring personal data is done in order to enable electronic communication including the interconnection of electronic systems</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>4. Amend Decision on Administrative Fees for OSK Services (12/2019) so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p> <p>6. Licensing fee of EUR 100 may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	<p>missing.</p> <p>The Decision on Administrative Fees in OSK (12/2019) should be amended to enable the payment in the end to avoid the frequency of and loss of time for payment, as well as to abolish the restriction to only one of form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.</p>
Chamber of Dentists of Kosovo (OSK)	OSK2-B	Specialist relicensing (of specialists of stomatology)	License	<p>Commission for Continuing Professional Education (CCPE) valorizes the credit points, the Licensing Commission is responsible for approval;</p> <p>License is signed by the Chair of the</p>	Same as license OSK1-A	<p>1. The OSK2-license should be issued for an indefinite term.</p> <p>2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</p> <p>3. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process.</p>	<p>There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-2020 on Permit and License System).</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
				Licensing Commission and the Chair of the Chamber		<p>4. OSK1-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained.</p> <p>5. Amend Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists, which establishes the right to appeal, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint.</p> <p>6. These changes can be made by amending Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists.</p> <p>7. Abolish the relicensing fee (EUR 100).</p>	
Chamber of Dentists of Kosovo (OSK)	OSK3	Permit for scientific bio-medical research	Permit	Ethical Commission; Permit is signed by the Chair of the Ethical Commission	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals does not regulate this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure is missing.</p> <p>4. Inappropriate and restricted payment method.</p> <p>5. The deadline for issuing the</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation No. 12/2019 (OSK) on the Scope and Competencies of the Ethical Commission, to require only information, to be submitted ex officio, without needing to submit documents such as: Copies of valid professional licenses of research participants, Applicant's work license.</p>	<p>Amendment of Law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of Regulation No. 12/2019 (OSK) on the Scope and Competencies of the Ethical Commission is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					license is missing	<p>3. Amend Regulation No. 12/2019 (OSK) on the Scope and Competencies of the Ethical Commission which establishes the right to appeal, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision on Administrative Fees in OSK (12/2019) so that the payment is made at the end of the procedure and is also done through e-banking, POS etc. Accept any proof of payment.</p> <p>5. Establish the deadline for procedure implementation and decision making for this type of license.</p> <p>6. The fees for this permit are very high (EUR 100-400) and may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) Fees should be determined depending on the load of work for the provision of this service and not according to the subject (natural or legal). It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).</p>	<p>procedures under the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copies of valid professional licenses of research participants is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision OSK (12/2019) should be done to enable payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.</p>
Chamber of	OSK4	License duplicate	Licence	Licensing Commission;	This license should not be included in the register as it is	1. Require only a request with minimum data to make known the fact of loss or damage of	There is no need and no argument for implementing a procedure and convening the

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Dentists of Kosovo (OSK)		(license copy)		License is signed by the Chair of the Commission and the Chair of the Chamber	not a new license	<p>the license.</p> <p>2. Other data are or should be in the register of licenses kept by the chamber.</p> <p>3. The duplicate copy should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p>	Licensing Commission to decide on an action as simple as the issuance of a duplicate copy, which can easily be ascertained and issued by the professional service of the Chamber.
Kosovo Chamber of Nurses (OIK)	OIK1-A	Licensing with secondary school	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure in the case of licensing is missing.</p> <p>4. The method of payment is more convenient but still restricted.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation to require only information, to be submitted ex officio, without needing to submit documents such as: Scanned ID card, Birth Certificate or Marriage Certificate (for married women) not older than 6-months.</p> <p>3. Amend Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision on Administrative Fees in OIK so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official</p>	<p>Amendment of law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of the Regulation is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision on Administrative Fees for OIK services should be done to enable</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						authorized for this purpose.	<p>payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The license register is necessary especially for tracking the relicensing time but also in case of loss or damage of a license to duplicate it.</p>
Kosovo Chamber of Nurses (OIK)	OIK1-B	Relicensing with secondary school	License	<p>Licensing Commission;</p> <p>License is signed by the Chair of the Licensing Commission and the Chair of the Chamber</p>	Same as license OIK1-A	<ol style="list-style-type: none"> The OIK1-A license should be issued for an indefinite term. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process. OIK1-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for 	<p>There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-202 on Permit and License System).</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>filing a complaint and deciding on the complaint.</p> <p>6. These changes can be made by amending the relevant Regulation.</p>	
Kosovo Chamber of Nurses (OIK)	OIK2-A	Licensing with college	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure in the case of licensing is missing.</p> <p>4. The method of payment is more convenient but still restricted.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend Regulation to require only information, to be submitted ex officio, without needing to submit documents such as: Scanning ID card, Birth Certificate or Marriage Certificate (for married women) not older than 6-months.</p> <p>3. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision on Administrative Fees in OIK so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p>	<p>Amendment of law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of the Regulation is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision on Administrative Fees for OIK Services should be done to enable payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						6. The licensing fee is EUR 60 (compared to the high school licensing which is EUR 20) and may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) Fees should vary according to the load of work for the provision of this service and not according to the education of the applicant. It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).	accordance with Article 18 of Law No. 04/L-202 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.
Kosovo Chamber of Nurses (OIK)	OIK2-B	Relicensing with college	License	Licensing Commission; License is signed by the Chair of the Licensing Commission and the Chair of the Chamber	Same as license OIK2-A	<ol style="list-style-type: none"> 1. The OIK2-B license should be issued for an indefinite term. 2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license. 3. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process. 4. OIK2-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, 	There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-202 on Permit and License System).

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>and the examination process can be continued to prove that the professional qualifications have been maintained.</p> <p>5. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>6. These changes can be made by amending the Regulation.</p>	
Kosovo Chamber of Nurses (OIK)	OIK3-A	Licensing with Bachelor	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation, but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure in the case of licensing is missing.</p> <p>4. The method of payment is more convenient but still restricted.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend the Regulation to require only information, to be submitted ex officio, without needing to submit documents such as: Scanning ID card, Certificate of Examination at the Ministry of Health, Birth Extract or Marriage Certificate (for married women) not older than 6 months.</p> <p>3. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision on Administrative Fees for OIK Services so that payment is made at</p>	<p>Amendment of law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of the Regulation is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a named document to a request such as instead of a copy of the identity card requiring personal data is done in order to enable electronic communication including the interconnection of electronic systems</p> <p>Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Decision on Administrative Fees for OIK Services should be done to enable</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p> <p>6. The licensing fee is EUR 60 (compared to the high school licensing which is EUR 20) and may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) Fees should vary according to the load of work for the provision of this service and not according to the education of the applicant. It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).</p>	<p>payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.</p>
Kosovo Chamber of Nurses (OIK)	OIK3-B	Relicensing with Bachelor	Licence	Licensing Commission; License is signed by the Chair of the Licensing Commission and the Chair of the Chamber	Same as license OIK3-A	<p>1. The OIK3-A license should be issued for an indefinite term.</p> <p>2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</p> <p>3. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to</p>	There is no need to implement the procedure as in the case of licensing for the first time since the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-2020 on Permit and License System).

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>be required because they exist and were provided during the first licensing process.</p> <p>4. OIK3-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained.</p> <p>5. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>6. These changes can be made by amending the Regulation.</p>	
Kosovo Chamber of Nurses (OIK)	OIK4-A	Licensing of clinical psychologists	Licence	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<p>1. Law No. 04/L-150 on Chambers of Healthcare Professionals, Article 9, paragraph 1.3, regulates only the competence of the chamber for licensing, relicensing and revocation but not this type of permit.</p> <p>2. Some of the documents do not need to be requested from the party.</p> <p>3. The appeal procedure in the case of licensing is missing.</p>	<p>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</p> <p>2. Amend the Regulation to require only information, to be submitted ex officio, without needing to submit documents such as: Scanning ID card, Certificate of Examination at the Ministry of Health, Birth Extract or Marriage Certificate (for married women) not older than 6 months.</p>	<p>Amendment of law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of Regulation is needed to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a named document to a request such as instead of a copy of the identity card requiring personal data is done in order to</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>4. The method of payment is more convenient but still restricted.</p>	<p>3. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>4. Amend Decision on Administrative Fees for OIK Services so that payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</p> <p>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</p> <p>6. The licensing fee is EUR 60 (compared to the high school licensing which is EUR 20) and may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) Fees should be determined depending on the load of work for the provision of this service and not according to the education of the applicant. It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).</p>	<p>enable electronic communication including the interconnection of electronic systems Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of the Decision on Administrative Fees for OIK Services should be done to enable payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System and should not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.</p>
Kosovo	OIK4-B	Relicensing of clinical	License	Licensing Commission;	Same as license OIK4-A	1. The OIK4-A license should be issued for an indefinite term.	There is no need to implement the procedure as in the case of licensing for the first time since

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Chamber of Nurses (OIK)		psychologists		License is signed by the Chair of the Licensing Commission and the Chair of the Chamber		<p>2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</p> <p>3. The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to be required because they exist and were provided during the first licensing process.</p> <p>4. OIK4-A license does not need to be changed if 100 credit points are reached; in this case it suffices to update the data in the license register. If 100 credit points are not reached, the first license can be revoked, and the examination process can be continued to prove that the professional qualifications have been maintained.</p> <p>5. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for filing a complaint and deciding on the complaint.</p> <p>6. These changes can be made by amending the Regulation No. 12/2019.</p>	the whole purpose of relicensing is to ascertain the requirements for holding a professional license (Article 10, par.3.5) and maintaining professional qualifications through continuing education (Article 13 of Law No. 04/L-202 on Permit and License System).
Kosovo Chamber of Nurses (OIK)	OIK5	Free licensing and relicensing for categories	/	/	/	This should not be included in the register and should not be treated as licensing	This is not licensing, but only exemption from payment of other licenses issued by the OIK

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		of war veterans, veterans, martyrs, war invalids, civilian victims and their families					
Kosovo Chamber of Nurses (OIK)	OIK6	License duplicate (license copy)	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	This should not be included in the register as it is not a new license	<ol style="list-style-type: none"> 1. Require only a request with minimum data to make known the fact of loss or damage of the license. 2. Other data are or should be in the register of licenses kept by the chamber. 3. The duplicate copy should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose. 	There is no need and no argument for implementing a procedure and convening the Licensing Commission to decide on an action as simple as the issuance of a duplicate copy, which can easily be ascertained and issued by the professional service of the Chamber.
Division for Licensing and Accreditation of Health care Institutions	DLAIS H1	License for general hospital	Permit	Board for Licensing of Private Healthcare Institutions; License is signed by the Minister and the Chair of the Board	<ol style="list-style-type: none"> 1. Law No. 04/L-125 on Health in Article 42 provides only for the obligation to be licensed to commence work but does not stipulate this type of license specifically; 2. Sub-legal acts that regulate this license, in addition to not having a clear legal basis, do not regulate it specifically; 3. The license is issued for a 	<ol style="list-style-type: none"> 1. Amend Law No. 04/L-125 on Health, listing in an annex all permits for which the Ministry of Health is competent. 2. Amend Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions, to require only information, to be submitted ex officio, without needing to submit documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel; 	Amendment of Law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law. Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions should be done to harmonize with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a registered document

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					<p>period of 5 years which is determined by sub-legal act and after the expiration of this term the relicensing must be done for which the same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the party.</p> <p>5. The right to appeal is regulated by a sub-legal act and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate, and payment is not refunded if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. Decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license is issued to a natural</p>	<p>3. Amend Administrative Instruction No. 08/2014 on the procedures for licensing private healthcare institutions, in order to grant this permit for an indefinite term, abolishing the validity period and the need for relicensing;</p> <p>4. Amend Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions which establishes the rules for eligibility of complaints, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LGAP.</p> <p>5. Amend administrative Instruction No. 08/2014 Procedures for licensing private healthcare institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof of payment. In case the issuance of this permit is refused, all payments made by the party should be refunded.</p> <p>6. Create/complete the license register with all the elements contained by the license.</p> <p>7. The permit must be signed by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LGAP.</p>	<p>to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions should be made to enable payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit/responsible official is an obligation under the LGAP because the substantive competence for this permit has been given to the MoH and therefore there is no need to create such boards;</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the requirements for premises, personnel and medical equipment is done by an evaluation commission appointed by the minister;</p> <p>11. There are no rules concerning suspension, revocation and transfer of this permit;</p>	<p>8. Transfer the decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</p> <p>9. Change the category of permit from license to permit.</p> <p>10. The evaluation of the fulfillment of the requirements for premises, personnel and medical equipment is done through the completion of a sworn statement without the need of visits by the evaluation commission.</p> <p>11. The rules of Law No. 04/L-202 on Permit and License System apply vis-a-vis suspension, revocation and transfer of this permit.</p> <p>12. The fee for issuing a permit is EUR 4,000 (EUR 1,500 for relicensing) and there is an additional application fee of EUR 1,000; these fees may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that the competent authority may charge for a permit will not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	<p>Submission of a sworn statement by the party proving fulfilment of the requirements for premises, personnel and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons: first, not to delay the procedure and waste time and money for both the party and institution; second, the evaluation does not guarantee that these conditions are met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						13. The fee for adding new hospital activity is also very high and needs to be reconsidered.	
Division for Licensing and Accreditation of Health care Institutions	DLAIS H2	License for specialized hospital	Permit	Board for Licensing of Private Healthcare Institutions; License is signed by the Minister and the Chair of the Board	<p>1. Law No. 04/L-125 on Health in Article 42 provides only for the obligation to be licensed to commence work, but it does not provide for this type of license specifically.</p> <p>2. Sub-legal acts that regulate this license, in addition to not having a clear legal basis, do not regulate it specifically.</p> <p>3. The license is issued for a period of 5 years which is determined by sub-legal act and after the expiration of this term the relicensing must be done for which the same procedure as for licensing must be followed.</p> <p>4. Some of the documents do not need to be requested from the party.</p> <p>5. The right to appeal is regulated by a sub-legal act and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely</p>	<p>1. Amend Law No. 04/L-125 on Health, listing in an annex all permits for which the Ministry of Health is competent.</p> <p>2. Amend Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions, to require only information, to be submitted ex officio, without needing to submit documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel.</p> <p>3. Amend Administrative Instruction No. 08/2014 on the procedures for licensing private healthcare institutions, so that this permit is issued for an indefinite term, abolishing the validity period and the need for relicensing;</p> <p>4. Amend Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions which establishes the rules for eligibility of complaints, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LGAP.</p> <p>5. Amend Administrative Instruction No.</p>	<p>Amendment of Law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions should be done to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions should be made to enable payment in the end to avoid frequency</p>

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					<p>absent.</p> <p>6. The method of payment is inappropriate, and payment is not refunded if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. Decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license is issued to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the requirements for premises, personnel and medical equipment is done through an evaluation commission appointed by the minister.</p> <p>11. There are no rules concerning suspension, revocation and transfer of this permit.</p>	<p>08/2014 Procedures for licensing private healthcare institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof of payment. In case the issuance of this permit is refused, all payments made by the party should be refunded.</p> <p>6. Create/complete the license register with all the elements contained in the license.</p> <p>7. The permit should be signed by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LGAP.</p> <p>8. Transfer decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</p> <p>9. Change the category of permit from license to permit.</p> <p>10. The evaluation of the fulfillment of the conditions of premises, personnel and the medical equipment should be done through the completion of a sworn statement without the need of visits by the evaluation commission.</p> <p>11. The rules of Law No. 04/L-202 on Permit and License System apply vis-a-vis</p>	<p>of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making responsibility to the unit/responsible official is an obligation under the LGAP because the substantive competence for this permit has been given to the MoH and therefore there is no need to create such boards.</p> <p>Submission of a sworn statement by the party proving fulfilment of the requirements for premises, personnel and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons: first, not to delay the procedure and waste time and money for both the party and institution; second, the evaluation does not guarantee that these conditions are met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>suspension, revocation and transfer of this permit.</p> <p>12. The fee for issuing a permit is EUR 3,000 (and EUR 1,500 for relicensing) and there is an additional application fee of EUR 1,000; these fees may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p> <p>13. The fee for adding new hospital activity is also very high and needs to be reconsidered.</p>	
Division for Licensing and Accreditation of Health Institutions	DLAIS H3	License for single activity ambulance (specialist ambulance)	Permit	<p>Board for Licensing of Private Healthcare Institutions;</p> <p>License is signed by the Minister and the Chair of the Board</p>	<p>1. Law No. 04/L-125 on Health in Article 42 provides only for the obligation to be licensed to commence work, but it does not provide for this type of license specifically.</p> <p>2. Sub-legal acts that regulate this license, in addition to not having a clear legal basis, do not regulate it specifically.</p> <p>3. The license is issued for a</p>	<p>1. Amend Law No. 04/L-125 on Health, listing in an annex all permits for which the Ministry of Health is competent.</p> <p>2. Amend Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions, to require only information, to be submitted ex officio, without needing to submit documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel</p>	<p>Amendment of law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions should be done to harmonize with Article 16 of Law No. 04/L-202 on Permit and License System, but also to ensure compliance with the principle of conducting ex officio procedures under the</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>period of 5 years which is determined by sub-legal act and after the expiration of this term the relicensing must be done for which the same procedure as for licensing must be followed.</p> <p>4. Some of the documents do not need to be requested from the party.</p> <p>5. The right to appeal is regulated by a sub-legal act and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate, and payment is not refunded if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. Decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license is issued to a natural</p>	<p>3. Amend Administrative Instruction No. 08/2014 on the procedures for licensing private healthcare institutions and to grant this permit to the unfortunate by deleting the validity period and the need for relicensing;</p> <p>4. Amend Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions which establishes the rules for eligibility of complaints, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LGAP.</p> <p>5. Amend Administrative Instruction No. 08/2014 Procedures for licensing private healthcare institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof of payment. In case the issuance of this permit is refused, all payments made by the party will be returned.</p> <p>6. Create/complete the license register with all the elements contained in the license.</p> <p>7. The permit should be signed by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LGAP.</p>	<p>LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions should be made to enable payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit/responsible official is an obligation under the LGAP because the substantive competence for this permit has been given to the MoH and therefore there is no need to create such</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister.</p> <p>11. There are no rules concerning suspension, revocation and transfer of this permit.</p>	<p>8. Transfer decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</p> <p>9. Change the category of permit from license to permit.</p> <p>10. The evaluation of the fulfillment of the requirements for premises, personnel and medical equipment should be done through the completion of a sworn statement without the need for visits by the evaluation commission.</p> <p>11. The rules of Law No. 04/L-202 on Permit and License System apply vis-a-vis suspension, revocation and transfer of this permit.</p> <p>12. The fee for issuing a permit is EUR 600 (and EUR 200 for relicensing) and there is an additional fee of EUR 200 for application; these fees may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	<p>boards;</p> <p>Submission of a sworn statement by the party proving fulfilment of the requirements for premises, personnel and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons: first, not to delay the procedure and waste time and money for both the party and institution; second, the evaluation does not guarantee that these conditions are met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Division for Licensing and Accreditation of Health care Institutions	DLAIS H4	License for ambulances with two activities	Permit	Board for Licensing of Private Healthcare Institutions; License is signed by the Minister and the Chair of the Board	<p>1. Law No. 04/L-125 on Health in Article 42 provides only the obligation to be licensed to start work but nowhere does it provide for this type of license specifically;</p> <p>2. Sub-legal acts that regulate this license, in addition to not having a clear legal basis, do not regulate it specifically;</p> <p>3. The license is issued for a period of 5 years which is determined by sub-legal act and after the expiration of this term the relicensing must be done for which the same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the party.</p> <p>5. The right to appeal is regulated by a sub-legal act and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p>	<p>1. Amend Law No. 04/L-125 on Health and in an annex to list all permits for which the Ministry of Health is competent.</p> <p>2. Amend Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions, to require only information, to be submitted ex officio, without needing to submit documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel.</p> <p>3. Amend Administrative Instruction No. 08/2014 on the procedures for licensing private healthcare institutions, to grant this permit for an indefinite term, abolishing the validity period and the need for relicensing.</p> <p>4. Amend Administrative Instruction No. 08/2014 Procedures for licensing of private healthcare institutions which establishes the rules for eligibility of complaints, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LGAP.</p> <p>5. Amend Administrative Instruction No. 08/2014 Procedures for licensing private healthcare institutions in order for payment to be made at the end of the procedure and</p>	<p>Amendment of law No. 04/L-125 on Health is needed to harmonize this Law with Article 17, paragraph, 1 of Law No. 04/L-202 on Permit and License System, according to which a permit and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for Licensing of Private Healthcare Institutions should be done to harmonize with Article 16 of Law No. 04/L-202 on Permit and License System but also to ensure compliance with the principle of conducting ex officio procedures under the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems. Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private healthcare institutions should be made to regulate the right to and procedure of appeal which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for Licensing of Private Healthcare Institutions should be made to enable payment in the end to avoid frequency of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>6. The method of payment is inappropriate, and no payment will be refunded if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. The way of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license is issued to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. There are no rules concerning suspension, revocation and transfer of this permit;</p>	<p>to be made through e-banking, POS, etc. Accept any proof of payment. In case the issuance of this permit is refused, all payments made by the party will be returned.</p> <p>6. Create/complete the license register with all the elements contained in the license.</p> <p>7. The permit should be signed by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LGAP.</p> <p>8. Transfer decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</p> <p>9. Change the category of permit from license to permit.</p> <p>10. The evaluation of the fulfillment of the requirements for premises, personnel and medical equipment should be done through the completion of a sworn statement without the need for visits by the evaluation commission.</p> <p>11. The rules of Law No. 04/L-202 on Permit and License System apply vis-a-vis suspension, revocation and transfer of this permit.</p>	<p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit/responsible official is an obligation under the LGAP because the substantive competence for this permit has been given to the MoH and therefore there is no need to create such boards;</p> <p>Submission of a sworn statement by the party proving fulfilment of the requirements for premises, personnel and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons: first, not to delay the procedure and waste time and money for both the party and institution; second, the evaluation does not guarantee that these conditions are met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						12. The fee for issuing a permit is EUR 800 (and EUR 400 for relicensing) and there is an additional fee of EUR 400 for application; these fees may not be in accordance with Article 18 of Law No. 04/L-2020 on Permit and License System (The fee that a competent authority may charge for a permission shall not exceed the amount required to cover the cost that the competent authority incurs in administering the permission). It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).	
Division for Licensing and Accreditation of Health Institutions	DLAIS H3	Ambulance license with one activity (specialist ambulance)	Permit	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<p>1. Law no. 04 / L-125 on Health in article 42 foresees only the obligation to be licensed to start work but nowhere does not foresee for this type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same</p> <p>3. The license is issued for a period of 5 years which is determined by the law and after the expiration of this term the relicensing must be done for which the same procedure as</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where only informations are required and the same have to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel;</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence without deadline by deleting the validity period and the need for relicensing;</p> <p>4.To amend the Administrative Instruction</p>	<p>Amendment of law no. 04 / L-125 on Health has to harmonize this law with article 17, paragraph 1 of Law no. 04 / L-202 on the system of permits and licenses according to which a permit and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of permits and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties.</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is lacking completely</p> <p>6. The method of payment is inconvenient and non-returnable.</p> <p>7. The register of licenses is lacking or incomplete.</p> <p>8. Manner of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. There are no rules for suspension, revocation and</p>	<p>No. 08/2014 Procedures for licensing of private health institutions in which are established the rules for the admissibility of the complaint, the procedure, the body reviewing the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions for way how the payment is made at the end of the procedure and is also made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party will be returned/returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains</p> <p>7. The signing of the licence to be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA;</p> <p>8. To change the way of decision making by the board in a unit / responsible official within the MoH as defined by the LPPA;</p> <p>9. To change the category of licence from license to licence;</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation</p>	<p>licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely lacking.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove . The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible officer, is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party for fulfilling the conditions for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment that will be made however does not guarantee that these conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					transfer of this licence;	<p>commission;</p> <p>11. For the rules for suspension, revocation and transfer of this licence to apply to those that are defined in Law no. 04 / L-202 on the system of licences.</p> <p>12. The fee for issuing a licence is 600 euros (for relicensing 200 euros) and there is an additional fee for application of 200 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences.(The fee that the competent authority may charge for a licence shall not exceed the necessary amount to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	
Division for Division for Licensing and Accreditation of Health care Institutions	DLAIS H4	License for ambulance with two activities	Permit	<p>Licensing Board of Private Health Care Institutions;</p> <p>The license is signed by: the Minister and the Chairman of the Board</p>	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligations to be licensed so they can start with work but nowhere does it provide the type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p> <p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where the only information is required and the same has to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel;</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this</p>	<p>Amendment of law no. 04 / L-125 on Health has to be in harmonized with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a permit and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of permits and licenses but also on the principles of conducting the procedure ex officio according to the LPPA. The change from a registered (named) document to a request, for example requesting personal data instead of a copy of the identity card, in order to enable</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>relicensing must be done for the same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAPwhile the deadline for decision-making on the complaint is completely lacking.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. The way of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the</p>	<p>licence without deadline by deleting the validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions in which is established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party shall be returned.</p> <p>6. To create / complete the license register with all the elements that the license contains.</p> <p>7. The signing of the licence to be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA;</p> <p>8. To change the way of decision making from the board in one unit / one responsible official within the MoH as defined by the LPPA;</p> <p>9. To change the category of permit from license to permit;</p> <p>10. The evaluation of the fulfillment of the</p>	<p>electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely lacking. Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / to a responsible officer is an obligation under the LGAPbecause the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving a sworn statement by a party to meet the requirements for space, medical staff and equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and wasting time and money for both the party and institution, the second assessment made however does not guarantee that these</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>minister;</p> <p>11. There are no rules for suspension, revocation and transfer of this licence;</p>	<p>conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. For the rules for suspension, revocation and transfer of this licence, to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. The fee for issuing a licence is 800 euros (for relicensing 400 euros) and there is an additional fee for application of 400 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of permits and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	<p>conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>
Division for Licensing and Accreditation of Health care Institutions	DLAIS H5	License for Polyclinic	Permit	<p>Licensing Board of Private Health Care Institutions;</p> <p>The license is signed by: the Minister and the Chairman of the Board</p>	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work but nowhere does it provide this type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions, where only informations are required and the same to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration,</p>	<p>Amendment of law no. 04 / L-125 on Health has to be harmonized with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the relicensing must be done with same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. The way of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of</p>	<p>professional licenses for health personnel;</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence without deadline by deleting the validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions in which are established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party will be returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains</p> <p>7. The signing of the licence has to be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA;</p> <p>8. To change the way of decision making from the board to one unit /or the responsible official within the MoH as</p>	<p>according to the LPPA. The change from a named document to a request such as instead of a copy of the identity card requiring personal data is done in order to enable electronic communication including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible officer is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. The rules for suspension, revocation and transfer of this licence are missing;</p>	<p>defined by the LPPA;</p> <p>9. To change the category of licence from licence to permit;</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. The fee for issuing a licence is 1,000 euros (for relicensing 500 euros) and there is an additional fee for application of 600 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of permits and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p> <p>13. The fee for adding new activity in the polyclinic is also high and should be reconsidered.</p>	<p>several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>
Division for Licensing and	DLAIS H6	License for family medicine center	Permit	Licensing Board of Private Health Care Institutions;	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work but nowhere does provide</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction</p>	<p>Amendment of law no. 04 / L-125 on Health has to be harmonized with article 17, paragraph 1 of Law no. 04 / L-202 on the system of permits and licenses according to which one permit and one</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Accreditation of Health care Institutions				The license is signed by: the Minister and the Chairman of the Board	<p>this type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p> <p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the relicensing must be done with the same procedure as for licensing;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely lacking.</p> <p>6. The method of payment is inappropriate and payments will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. Manner of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as</p>	<p>No. 08/2014 Procedures for licensing private health institutions, where only informations are required and the same are to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel;</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence without deadline by deleting the validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions in which are established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payments to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party shall be returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains</p>	<p>license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be harmonized with Article 16 of Law no. 04 / L-202 on the system of permits and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered (named) document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely lacking.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible officer is an obligation under the LGAP because the substantive competence for</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation for the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. There are no rules for suspension, revocation and transfer of this licence;</p>	<p>7. The signing of the licence to be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA;</p> <p>8. To change the way of decision making from the board to one unit /one responsible official within the MoH as defined by the LPPA;</p> <p>9. To change the category of permit from license to permit;</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment shall be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p>	<p>this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p>
Division for Licensing and Accreditation of Health care Institutions	DLAIS H7	Licence for Laboratory	Permit	<p>Licensing Board of Private Health Care Institutions;</p> <p>The license is signed by: the Minister and the Chairman of the Board</p>	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work but nowhere does it provide for this type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p> <p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the relicensing must be done for</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where only information is required and the same to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel;</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence without deadline by deleting the</p>	<p>Amendment of law no. 04 / L-125 on Health is needed to harmonize this law with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered/named document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>which the same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. Manner of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment are done through an evaluation commission appointed by the minister;</p>	<p>validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions on which are established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party to be returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains.</p> <p>7. The signing of the licence to be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA;</p> <p>8. To change the way of decision making from the board to one unit /or one responsible official within the MoH as defined by the LPPA;</p> <p>9. To change the category of permit from license to permit;</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment to be done through</p>	<p>interconnection of electronic systems. Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing private health institutions should be made to regulate the right and procedure of the complaint which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible official is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these conditions can be met from the first days,</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					11. There are no rules for suspension, revocation and transfer of this licence;	<p>the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. The fee for issuing a licence is 1,000 euros (for relicensing 400 euros) and there is an additional fee for application of 200 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.
Division for Licensing and Accreditation of Health care Institutions	DLAIS H8	License for radiology cabinet	Permit	<p>Licensing Board of Private Health Care Institutions;</p> <p>The license is signed by: the Minister and the Chairman of the Board</p>	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work, but nowhere does it provide this type of license specifically;</p> <p>2. The bylaws that regulate this license, except that they do not have a clear legal basis, do not regulate it in the same way in a certain way;</p> <p>3. The license is issued for a period of 5 years which is</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where only information is required and the same to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel;</p> <p>3. To amend the Administrative Instruction</p>	<p>Amendment of law no. 04 / L-125 on Health has to be harmonized with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a permit and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of permit and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered/named document to a request, such</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>determined by bylaw and after the expiration of this term the relicensing must be done following same procedure as for licensing;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. Manner of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done</p>	<p>No. 08/2014 on the procedures for licensing private health institutions and to grant this licence to the without deadline by deleting the validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions in which are established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party shall be returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains.</p> <p>7. The signing of the licence to be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA;</p> <p>8. To change the way of decision making from the board to one unit / responsible official within the MoH as defined by the LPPA;</p>	<p>as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment. The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible official is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards; Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>through an evaluation commission appointed by the minister;</p> <p>11. There are no rules for suspension, revocation and transfer of this licence;</p> <p>12. Administrative Instruction No. 03/2007 The application of ionizing and non-ionizing rays in health is based on the Law on Private Health Activities which has been repealed by Law no. 04 / L-125 on Health.</p>	<p>9. To change the category of licence from permit to licence;</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. To repeal the Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health and to approve the new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health.</p> <p>13. The fee for issuing a licence is 1,000 euros (for relicensing 400 euros) and there is an additional fee for application of 200 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	<p>conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p> <p>Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health really without legal basis, therefore the same should be repealed, a new administrative instruction is drafted.</p>
Division for	DLAIS H9	License for Radiology-	Permit	Licensing Board of Private Health	1. Law no. 04 / L-125 on Health in article 42 provides only the	1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which	Amendment of law no. 04 / L-125 on Health is needed to harmonize this law with article 17,

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Licensing and Accreditation of Health care Institutions		Dentistry cabinet		Care Institutions; The license is signed by: the Minister and the Chairman of the Board	obligation to be licensed to start work, but nowhere does it provide this type of license specifically; 2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same; 3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the relicensing must be done for which the same procedure as for licensing must be followed; 4. Some of the documents do not need to be requested from the parties 5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent. 6. The method of payment is inappropriate and payment will not be returned if the license is denied. 7. The register of licenses is missing or incomplete. 8. The way of decision making	the Ministry of Health is competent. 2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where only information are required and the same are provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel; 3. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions and this licence to be given without deadline by deleting the validity period and the need for relicensing; 4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions in which is established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LGAP 5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party will be returned. 6. To create / complete the license register	paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law. Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems. Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely missing. Amending the Administrative Instruction No. 08/2014 on Procedures for licensing private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment. The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies. Delegation of decision-making to the unit /

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. There are no rules for suspension, revocation and transfer of this licence;</p> <p>12. Administrative Instruction No. 03/2007 The application of ionizing and non-ionizing rays in health is based on the Law on Private Health Activities which has been repealed by Law no. 04 / L-125 on Health.</p>	<p>with all the elements that the licence contains</p> <p>7. The signing of the licence to be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA;</p> <p>8. To change the way of decision making by the board in a unit / responsible official within the MoH as defined by the LPPA;9. Te ndryshohet kategoria e lejimi nga licence ne leje;</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. To repeal the Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health and to approve the new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health.</p> <p>13. The fee for issuing a licence is 800 euros (for relicensing 300 euros) and there is an additional fee for application of 200 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences and licenses (The fee that</p>	<p>responsible officer is an obligation under the LGAPbecause the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p> <p>Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health really without legal basis, therefore the same should be repealed, a new administrative instruction is drafted.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).	
Division for Licensing and Accreditation of Health care Institutions	DLAIS H10	License for ultrasound cabinet	Permit	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work but nowhere does it provide for this type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p> <p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the relicensing must be done for which the same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where only information is required and the same to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, Professional licenses for health personnel.</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence to the without deadline by deleting the validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions in which is established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p>	<p>Amendment of law no. 04 / L-125 on Health is needed to harmonize this law with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. The way of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. There are no rules for suspension, revocation and transfer of this licence;</p> <p>12. Administrative Instruction No. 03/2007 The application of ionizing and non-ionizing rays in health is based on the Law on Private Health Activities which has been repealed by Law no. 04 / L-125 on Health.</p>	<p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party will be returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains</p> <p>7. The signing of the licence should be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA.</p> <p>8. To change the way of decision-making by the board in a unit / responsible official within the MoH as defined by the LPPA.</p> <p>9. To change the category of permission from license to licence.</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment should be done by filling in an affidavit without the need to make visits by the evaluation commission.</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. To repeal the Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health and to approve the</p>	<p>of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible officer is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p> <p>Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health really without legal basis, therefore the same should be repealed, a new administrative instruction is drafted</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health.</p> <p>12. The fee for issuing a licence is 600 euros (for relicensing 200 euros) and there is an additional fee for application of 200 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	
Division for Licensing and Accreditation of Health care Institutions	DLAIS H11	Cabinet license for computed tomography	Permit	<p>Licensing Board of Private Health Care Institutions;</p> <p>The license is signed by: the Minister and the Chairman of the Board</p>	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work but nowhere does it provide for this type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p> <p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the relicensing must be done for which the same procedure as</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where only the information is required and the same to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Business registration certificate, Professional licenses for health personnel.</p> <p>3. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions and this licence to be given without deadline by deleting the</p>	<p>Amendment of law no. 04 / L-125 on Health is needed to harmonize this law with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be harmonized with Article 16 of Law no. 04 / L-202 on the system of permits and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p>

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					<p>for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. The way of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. There are no rules for</p>	<p>validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No.08/2014 Procedures for licensing private health institutions in which are established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>6. To create / complete the license register with all the elements that the licence contains.</p> <p>7. The signing of the licence should be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA.</p> <p>8. To change the way of decision-making by from the board in one unit / one responsible official within the MoH as defined by the LPPA.</p> <p>9. To change the category of permission from license to permit.</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. To repeal the Administrative Instruction</p>	<p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be harmonized with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered/named document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further more the amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health ,have to be done to regulate the right and the complain procedure which lacks completely.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible officer is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the</p>

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					<p>suspension, revocation and transfer of this licence;</p> <p>12. Administrative Instruction No. 03/2007 The application of ionizing and non-ionizing rays in health is based on the Law on Private Health Activities which has been repealed by Law no. 04 / L-125 on Health.</p>	<p>No. 03/2007 Application of ionizing and non-ionizing rays in health and to approve the new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health.</p> <p>13. The fee for issuing a licence is 1500 euros (for relicensing 700 euros) and there is an additional fee for application of 200 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	<p>procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p> <p>Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health really without legal basis, therefore the same should be repealed, a new administrative instruction is drafted.</p>
Division for Licensing and Accreditation of Health care Institutions	DLAIS H12	License for magnetic resonance cabinet	Permit	<p>Licensing Board of Private Health Care Institutions;</p> <p>The license is signed by: the Minister and the Chairman of the Board</p>	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work but nowhere does it provide for this type of license specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p> <p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions, where only information is required and the same to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, Professional licenses for health personnel.</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this</p>	<p>Amendment of law no. 04 / L-125 on Health is needed to harmonize this law with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law.</p> <p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio according to the LPPA. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable</p>

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					<p>relicensing must be done for which the same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. The way of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the</p>	<p>licence to the without deadline by deleting the validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions in which is established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party will be returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains</p> <p>7. The signing of the licence should be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA.</p> <p>8. To change the way of decision-making by the board in a unit / responsible official within the MoH as defined by the LPPA.</p> <p>9. To change the category of permission from license to licence.</p> <p>10. The evaluation of the fulfillment of the</p>	<p>electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely missing.</p> <p>Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible officer is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>minister;</p> <p>11. There are no rules for suspension, revocation and transfer of this licence;</p> <p>12. Administrative Instruction No. 03/2007 The application of ionizing and non-ionizing rays in health is based on the Law on Private Health Activities which has been repealed by Law no. 04 / L-125 on Health.</p>	<p>conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. To repeal the Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health and to approve the new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health</p> <p>13. The fee for issuing a licence is 1500 euros (for relicensing 700 euros) and there is an additional fee for application of 200 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).</p>	<p>conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p> <p>Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health really without legal basis, therefore the same should be repealed, a new administrative instruction is drafted.</p>
Division for Licensing and Accredited	DLAIS H13	License for coronary angiography and angiography cabinet	Permit	Licensing Board of Private Health Care Institutions; The license is	<p>1. Law no. 04 / L-125 on Health in article 42 provides only the obligation to be licensed to start work but nowhere does it provide for this type of license</p>	<p>1. To amend law no. 04 / L-125 on Health and in an annex to list all licences for which the Ministry of Health is competent.</p> <p>2. To change the Administrative Instruction No. 08/2014 Procedures for licensing of</p>	<p>Amendment of law no. 04 / L-125 on Health is needed to harmonized with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry of Health care Institutions				signed by: the Minister and the Chairman of the Board	<p>specifically;</p> <p>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</p> <p>3. The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the relicensing must be done, for which the same procedure as for licensing must be followed;</p> <p>4. Some of the documents do not need to be requested from the parties</p> <p>5. The right to appeal is regulated by a bylaw and the deadline for filing a complaint is shorter than defined by the LGAP while the deadline for decision-making on the complaint is completely absent.</p> <p>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is missing or incomplete.</p> <p>8. The way of decision making through a licensing board is unnecessary.</p> <p>9. The designation is incorrect as</p>	<p>private health institutions, where only information is required and the same to be provided ex officio and not documents such as: Identification documentation for the founder, director and health personnel, Certificate of business registration, Professional licenses for health personnel.</p> <p>3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence to the without deadline by deleting the validity period and the need for relicensing;</p> <p>4. To amend the Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions in which is established the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.</p> <p>5. To amend the Administrative Instruction No. 08/2014 Procedures for licensing private health institutions in order for payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party will be returned.</p> <p>6. To create / complete the license register with all the elements that the licence contains</p>	<p>Amendment of Administrative Instruction No. 08/2014 Procedures for licensing of private health institutions should be done to harmonize with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio according to the LGAP. The change from a registered document to a request, such as requesting personal data instead of a copy of the identity card, is done in order to enable electronic communication, including the interconnection of electronic systems.</p> <p>Further, the amendment of the Administrative Instruction No. 08/2014 on Procedures for licensing of private health institutions should be made to regulate the right and procedure of the complaint which is completely missing.</p> <p>Amending the Administrative Instruction No. 08/2014 on Procedures for licensing private health institutions should be made to enable payment in the end to avoid frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making to the unit / responsible official is an obligation under the LGAP because the substantive competence for this licence has been given to the MoH and</p>

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					<p>a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister;</p> <p>11. There are no rules for suspension, revocation and transfer of this licence;</p> <p>12. Administrative Instruction No. 03/2007 The application of ionizing and non-ionizing rays in health is based on the Law on Private Health Activities which is repealed by Law no. 04 / L-125 on Health.</p>	<p>7. The signing of the licence should be done by the head of the unit, respectively the responsible official in the MoH appointed in accordance with the LPPA.</p> <p>8. To change the way of decision-making by the board in a unit / responsible official within the MoH as defined by the LPPA.</p> <p>9. To change the category of permission from license to licence.</p> <p>10. The evaluation of the fulfillment of the conditions for the space, the personnel and the medical equipment to be done through the completion of an affidavit without the need to make visits by the evaluation commission;</p> <p>11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p> <p>12. To repeal the Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health and to approve the new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health.</p> <p>13. The fee for issuing a licence is 1500 euros (for relicensing 700 euros) and there is an additional fee for application of 500 euros; these taxes may not be in accordance with Article 18 of Law no. 04 / L-2020 on the system of licences and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount</p>	<p>therefore there is no need to create such boards;</p> <p>Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an assessment by an evaluation commission for several reasons, the first not to delay the procedure and waste time and money for both the party and institution, the second assessment made however does not guarantee that these conditions can be met from the first days, therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.</p> <p>Administrative Instruction No. 03/2007 Application of ionizing and non-ionizing rays in health really without legal basis, therefore the same should be repealed, a new administrative instruction is drafted.</p>

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						necessary to cover the costs incurred by the competent authority to administer the licence.) It is recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance with this).	
Department of Strategic Health Development	DZHSS H1	Temporary work licence for foreign doctors	License	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<ol style="list-style-type: none"> 1. Law no. 04 / L-125 on Health in article 71 paragraph 3 provides the obligation to be licensed according to the bylaw approved by the Government. This law nowhere specifically provides for this type of license specifically; 2. Administrative Instruction no. 06/2012 on Temporary Licensing of non-Kosovar civic health professionals is old and has no clear legal basis; 3. The license is issued for a period of 6 months but also shorter when the term is shorter for a residence licence which is determined by bylaw and after the expiration of this term the relicensing must be done for which the same procedure as for licensing must be followed; 4. Some of the documents do not need to be requested from the parties 5. There are no rules for the right to appeal; 6. The method of payment is 	<ol style="list-style-type: none"> 1. To amend law no. 04 / L-125 on Health to regulate this license or to refer to Article 12 of Law no. 04 / L-202 on the system of licences and licenses. 2. To draft and approve the bylaw according to article 71 paragraph 3 of Law no. 04 / L-125 on Health 3. This type of license to be granted indefinitely. 4. The bylaw for licensing of foreign national doctors to regulate only the requests where only the information is required according to paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses. 5. By bylaw to establish rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LPPA. 6. The bylaw to enable the payment to be made at the end of the procedure and to be made through e-banking, POS, etc. Accept any proof proving payment. In case the issuance of this licence is refused, all payments made by the party will be returned. 7. To create / complete the license register 	<p>Amendment of law no. 04 / L-125 on Health is needed to harmonize this law with article 17, paragraph 1 of Law no. 04 / L-202 on the system of licences and licenses according to which a licence and license can be defined only by law.</p> <p>The drafting and approval of the bylaw must be done in order to fulfill the legal requirement defined in paragraph 3 of article 71 of law no. 04 / L-125 on Health. The same must contain the information according to paragraph 12 of Law no. 04 / L-202 on the system of licences and licenses in order to harmonize with Article 16 of Law no. 04 / L-202 on the system of licences and licenses but also on the principle of conducting the procedure ex officio according to the LPPA.</p> <p>The bylaw should regulate the right and the procedure of the complaint which is completely missing as well as to define rules to enable the payment in the end to avoid the frequency and loss of time for payment and on the other hand not to limit only one form of evidence to prove payment.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>The restriction of the submission of the request</p>

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					<p>inappropriate and payment will not be returned if the license is denied.</p> <p>7. The register of licenses is lacking or incomplete.</p> <p>8. The request is made by the legal person for the foreign citizen and not by the natural person requesting the licence</p> <p>9. The designation is incorrect as a licence which refers to a natural person for engaging in a profession that poses a medium or high risk to public health.</p> <p>10. There are no rules for the suspension and revocation of this license.</p>	<p>with all the elements that the licence contains</p> <p>8. The request to be allowed for the natural person in this case by the doctor with foreign citizenship;</p> <p>9. To change the category of licence from licence to professional permit.</p> <p>10. The rules for suspension, revocation of this licence to apply those defined in Law no. 04 / L-202 on the system of licences and licenses.</p>	<p>by the legal entity only is without any argument. Rules for suspension and revocation are necessary even as a reference to Law no. 04 / L-202 on the system of licences and licenses.</p>
Kosovo Medicines Agency	AKPP M1	License for pharmaceutical retailers (pharmacies) of medicinal products and medical devices	Permit	<p>Licensing Department of the KMA;</p> <p>Licence is signed by the Director and the CEO of KMA</p>	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 14 paragraph 1.2, but it does not regulate the criteria and the procedure for issuing such permit, specifying that it be regulated by sub-legal act;</p> <p>2. The license is issued for a period of 5 years which is determined by sub-legal act and after the expiration of this term the relicensing must be done following the same procedure as for licensing;</p>	<p>1. Amend Law No 04/L-190 on Medicinal Products and Medical Devices to establish the conditions and criteria for this type of permission;</p> <p>2. Amend Administrative Instruction (MoH) No. 11/2015 on Retailers for medicinal products and medical devices to foresee the granting of this permit for an indefinite term, abolishing the validity period and the need for relicensing;</p> <p>3. Amend Administrative Instruction (MoH) No. 11/2015 on Retailers for medicinal products and medical devices, to require only information to be provided ex officio, without the need to submit documents such as: Business Certificate and information on</p>	<p>Amendment of Law No. 04/L-190 on Medicinal Products and Medical Devices is needed to harmonize it with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System according to which a permit and license can be defined only by law, including the main conditions and criteria.</p> <p>The only reason why re-licensing should be done is the payment therefore the need for re-licensing is unjustifiable and an unnecessary burden for applicants.</p> <p>Amendment of Administrative Instruction (MoH) No.11 / 2015 on Retailers for medicinal products and medical devices is needed so that it contains the information according to paragraph 12 of Law No. 04/L-202 on Permit</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>3. Some of the documents do not need to be requested from the party.</p> <p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permit, which is contrary to Article 12 of the LGAP.</p> <p>6. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked;</p> <p>7. The license register is missing or incomplete.</p> <p>8. The designation is incorrect as a license is issued to natural persons for engaging in a profession that poses a medium or high risk to public health.</p> <p>9. The evaluation of the fulfillment of some criteria is done in the field by senior officials of KMA; this is an obligatory phase of the procedure and is paid;</p> <p>10. The rules for revocation and transfer of this permit are missing.</p>	<p>business issued with code of activity for retail circulation of pharmaceutical products, Professional license of pharmacist, Work license of other professional staff;</p> <p>4. Amend Law No 04/L-190 on Medicinal Products and Medical Devices establishing the rules for complaint eligibility, the procedure, the body that reviews the complaint, and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP;</p> <p>5. Amend Law No 04/L-190 on Medicinal Products and Medical Devices to abolish all service fees, while licensing fees should be set in accordance with Article 12 of the LGAP and Article 18 of Law No. 04/L-202 on Permit and License System (The fee that the competent authority may charge for a permit shall not exceed the amount necessary to cover the costs incurred by the competent authority to administer the permit). Allow payment at the end of the procedure including through e-banking, POS, etc. Accept any proof of payment. In case the issuance of this permit is refused, all payments made by the party should be refunded;</p> <p>6. Create/complete the register of licenses with all the elements contained in the license;</p> <p>7. Change the way of decision-making for this license and delegate responsibility to the professional employee as provided for in</p>	<p>and License System and is in aligned with Article 16 of Law No. 04/L-202 on Permit and License System, as well as to ensure compliance with the principle of conducting the procedure ex officio according to the LGAP.</p> <p>Amendment of Law No. 04/L-190 on Medicinal Products and Medical Devices is needed is needed to regulate the right to and the procedure of complaint, which is completely missing</p> <p>Amendment of Law No. 04/L-190 on Medicinal Products and Medical Devices is needed should abolish all service fees while license fees should be determined according to Article 12 of the LGAP, as well as set rules to enable payment at the end to avoid frequency and loss of time for payment and abolishing, on the other hand, the restriction of only form of payment proof accepted.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making competencies is a legal requirement of the LGAP, including the signing of the license.</p> <p>Revocation rules are necessary, even if only as a reference to Law No. 04/L-202 on Permit and License System.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>Article 26 of the LGAP. This license should be signed by the head of the unit, respectively the responsible official of the KMA appointed in accordance with the LGAP;</p> <p>9. Change the category of permission from license to permit;</p> <p>10. Allow evaluation of the fulfillment of the conditions and criteria by completing a sworn statement without the need of visits from senior officials of the KMA;</p> <p>11. The rules defined in Law No. 04/L-202 on Permit and License System apply vis-a-vis revocation and transfer of this permit.</p>	
Kosovo Medicines Agency	AKPP M2	License for pharmaceutical wholesalers (warehouses) of medicinal products and medical devices	Permit	<p>Licensing Department of the KMA;</p> <p>Licence is signed by the Director and the CEO of KMA</p>	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 14 paragraph 1.2, but it does not regulate the criteria and the procedure for issuing such permit, specifying that it be regulated by sub-legal act;</p> <p>2. The license is issued for a period of 5 years which is determined by sub-legal act and after the expiration of this term the relicensing must be done following the same procedure as for licensing;</p> <p>3. Some of the documents do not need to be requested from the party.</p> <p>4. The right to appeal is not fully</p>	<p>1. Amend Law No 04/L-190 on Medicinal Products and Medical Devices to establish the conditions and criteria for this type of permission;</p> <p>2. Amend Administrative Instruction (MoH) No. 11/2015 on Retailers for medicinal products and medical devices to foresee the granting of this permit for an indefinite term, abolishing the validity period and the need for relicensing;</p> <p>3. Amend Administrative Instruction (MoH) No. 11/2015 on Retailers for medicinal products and medical devices, to require only information to be provided ex officio, without the need to submit documents such as: Business Certificate and information on business issued with code of activity for retail circulation of pharmaceutical products, Professional license of pharmacist, Work license of other professional staff;</p>	<p>Amendment of Law No. 04/L-190 on Medicinal Products and Medical Devices is needed to harmonize it with Article 17, paragraph 1, of Law No. 04/L-202 on Permit and License System according to which a permit and license can be defined only by law, including the main conditions and criteria.</p> <p>The only reason why re-licensing should be done is the payment therefore the need for re-licensing is unjustifiable and an unnecessary burden for applicants.</p> <p>Amendment of Administrative Instruction (MoH) No.11 / 2015 on Retailers for medicinal products and medical devices is needed so that it contains the information according to paragraph 12 of Law No. 04/L-202 on Permit and License System and is in aligned with Article 16 of Law No. 04/L-202 on Permit and License System, as well as to ensure compliance with the principle of conducting the procedure ex</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permit, which is contrary to Article 12 of the LGAP.</p> <p>6. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked;</p> <p>7. The license register is missing or incomplete.</p> <p>8. The designation is incorrect as a license is issued to natural persons for engaging in a profession that poses a medium or high risk to public health.</p> <p>9. The evaluation of the fulfillment of some criteria is done in the field by senior officials of KMA; this is an obligatory phase of the procedure and is paid;</p> <p>10. The rules for revocation and transfer of this permit are missing.</p>	<p>4. Amend Law No 04/L-190 on Medicinal Products and Medical Devices establishing the rules for complaint eligibility, the procedure, the body that reviews the complaint, and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP;</p> <p>5. Amend Law No 04/L-190 on Medicinal Products and Medical Devices to abolish all service fees, while licensing fees should be set in accordance with Article 12 of the LGAP. Allow payment at the end of the procedure including through e-banking, POS, etc. Accept any proof of payment. In case the issuance of this permit is refused, all payments made by the party should be refunded;</p> <p>6. Create/complete the register of licenses with all the elements contained in the license;</p> <p>7. Change the way of decision-making for this license and delegate responsibility to the professional employee as provided for in Article 26 of the LGAP. This license should be signed by the head of the unit, respectively the responsible official of the KMA appointed in accordance with the LGAP;</p> <p>9. Change the category of permission from license to permit;</p> <p>10. Allow evaluation of the fulfillment of the conditions and criteria by completing a sworn statement without the need of visits from senior officials of the KMA;</p>	<p>officio according to the LGAP.</p> <p>Amendment of Law No. 04/L-190 on Medicinal Products and Medical Devices is needed is needed to regulate the right to and the procedure of complaint, which is completely missing</p> <p>Amendment of Law No. 04/L-190 on Medicinal Products and Medical Devices is needed should abolish all service fees while license fees should be determined according to Article 12 of the LGAP, as well as set rules to enable payment at the end to avoid frequency and loss of time for payment and abolishing, on the other hand, the restriction of only form of payment proof accepted.</p> <p>The register of licenses is necessary especially in case of loss or damage of a license to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>Delegation of decision-making competencies is a legal requirement of the LGAP, including the signing of the license.</p> <p>Revocation rules are necessary, even if only as a reference to Law No. 04/L-202 on Permit and License System.</p>

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						11. The rules defined in Law No. 04/L-202 on Permit and License System apply vis-a-vis revocation and transfer of this permit.	
Kosovo Medicines Agency	AKPP M3	License for the import of medicinal products	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 12 but not with a specific name;</p> <p>2. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>3. There is no need for some of the documents to be requested from the party.</p> <p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>6. In addition to service fees, a fee of 1% of the imported products' invoice value is envisaged;</p> <p>7. The Registry for Licenses is missing or is incomplete.</p>	<p>1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, listing in an annex all prerequisite permits or licences needed to obtain an import license, along with the conditions and criteria for obtaining those permits/licenses</p> <p>2. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p>	<p>The amendment of Law 04/L-190 on Medicinal Products and Medical Devices is needed in order to harmonize this law with Article 17, paragraph 1 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit and license can be defined only by law, including the main conditions and criteria. No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law no. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of the Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable</p>

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					<p>8. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>9. The rules for revocation and transfer of this permit are missing.</p>	<p>4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>5. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>6. Remove the tariff at the amount of 1% of the imported products.</p> <p>7. Establish/complete the Registry for Licenses with all the elements that the license contains.</p> <p>8. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>9. Change the permission category from license to permit;</p> <p>10. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no legal basis and no justification is provided as to why it should be paid. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Kosovo Medicines Agency	AKPP M5	License for the import of refurbished equipment	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices mentions this type of permit in Article 12 but not with a specific name;</p> <p>2. The license is issued for a period of 3 months with the possibility of extension for another 3 months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>3. Some of the documents are not necessary to be requested from the party.</p> <p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>6. In addition to service fees, a fee of 1% of the invoice value of imported products is envisaged;</p> <p>7. The register of licenses is missing or is incomplete.</p> <p>8. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to</p>	<p>1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, listing in an annex all prerequisite permits or licences needed to obtain an import license, along with the conditions and criteria for obtaining those permits/licenses;</p> <p>2. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of</p>	<p>The amendment of Law 04/L-190 on Medicinal Products and Medical Devices is needed in order to harmonize this law with Article 17, paragraph 1 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit and license can be defined only by law, including the main conditions and criteria. No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law no. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>public health is improper.</p> <p>9. The rules for revocation and transfer of this permit are missing.</p>	<p>the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>5. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>6. Remove the tariff at the amount of 1% of the imported products.</p> <p>7. Establish/complete the Registry for Licenses with all the elements that the license contains.</p> <p>8. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>9. Change the permission category from license to permit;</p> <p>10. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no legal basis and no justification is provided as to why it should be paid.</p> <p>The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP.</p> <p>The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>
Kosovo Medici	AKPP M6	License for the import of parallel	Permit	KMA Licensing Department;	1. Law No. 04/L-190 on Medicinal Products and Medical Devices mentions this type of	1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, listing in an annex all prerequisite permits or licences	The amendment of Law 04/L-190 on Medicinal Products and Medical Devices is needed in order to harmonize this law with Article 17, paragraph

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Pharmaceutical Agency		Importation of medicinal products (not registered in Kosovo)		The license is signed by: KMA Director and Chief Executive	<p>1. The license is issued as a permit in Article 12 but not with a specific name;</p> <p>2. The license is issued for a period of 3 months with the possibility of extension for another 3 months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>3. Some of the documents are not necessary to be requested from the party.</p> <p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>6. In addition to service fees, a fee of 1% of the invoice value of the imported products is envisaged;</p> <p>7. The register of licenses is missing or is incomplete.</p> <p>8. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>9. The rules for revocation and</p>	<p>1. The license is needed to obtain an import license, along with the conditions and criteria for obtaining those permits/licenses</p> <p>2. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the</p>	<p>1 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit and license can be defined only by law, including the main conditions and criteria. No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law no. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					transfer of this permit are missing.	<p>complaint in accordance with the LGAP.</p> <p>5. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>6. Remove the tariff at the amount of 1% of the imported products.</p> <p>7. Establish/complete the Registry for Licenses with all the elements that the license contains.</p> <p>8. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>9. Change the permission category from license to permit;</p> <p>10. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>legal basis and no justification is provided as to why it should be paid.</p> <p>The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP.</p> <p>The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>
Kosovo Medicines Agency	AKPP M7	License for import of narcotic medicinal products	Permit	KMA Licensing Department; The license is signed by: KMA	1. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this	1. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite	<p>No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>Amendment of Administrative Instruction No.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
y				Director and Chief Executive	<p>period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>2. Some of the documents are not necessary to be requested from the party.</p> <p>3. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>5. In addition to service fees, a fee of 1% of the imported products invoice value is envisaged; 6. The Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The rules for revocation and transfer of this permit are missing.</p>	<p>period by removing the validity period and the need for relicensing; 2. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards; 3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP. 4. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which</p>	<p>06/2014, Determination of the List of Medicinal Products and Borderline Products, should be done in order that it contains the information according to paragraph 12 of Law No. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no legal basis and no justification is provided as to why it should be paid. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is</p>

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						<p>confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>5. Remove the tariff at the amount of 1% of the imported products.</p> <p>6. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>7. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>8. Change the permission category from license to permit;</p> <p>9. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>
Kosovo Medicines Agency	AKPP M8	License for import of pharmaceuticals	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 12 but not with a specific name;</p> <p>2. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p>	<p>1. 1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, listing in an annex all prerequisite permits or licences needed to obtain an import license, along with the conditions and criteria for obtaining those permits/licenses</p> <p>2. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical</p>	<p>The amendment of Law 04/L-190 on Medicinal Products and Medical Devices is needed in order to harmonize this law with Article 17, paragraph 1 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit and license can be defined only by law, including the main conditions and criteria. No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>3. Some of the documents are not necessary to be requested from the party.</p> <p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>6. In addition to service fees, a fee of 1% of the imported products invoice value is envisaged;</p> <p>7. The register of licenses is missing or is incomplete.</p> <p>8. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>9. The rules for revocation and transfer of this permit are missing.</p>	<p>Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>5. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p>	<p>be made in order that it contains the information provided in paragraph 12 of the Law no. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no legal basis and no justification is provided as to why it should be paid. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. Delegation of the decision-making competency, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>6. Remove the tariff at the amount of 1% of the imported products.</p> <p>7. Establish/complete the Registry for Licenses with all the elements that the license contains.</p> <p>8. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>9. Change the permission category from license to permit;</p> <p>10. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	reference to Law No. 04/L-202 on Permit and License System.
Kosovo Medicines Agency	AKPP M9	License for import of denatured alcohol	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 12 but not with a specific name;</p> <p>2. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>3. Some of the documents are not necessary to be requested from the party.</p>	<p>1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, listing in an annex all prerequisite permits or licences needed to obtain an import license, along with the conditions and criteria for obtaining those permits/licenses;</p> <p>2. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products</p>	<p>The amendment of Law 04/L-190 on Medicinal Products and Medical Devices is needed in order to harmonize this law with Article 17, paragraph 1 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit and license can be defined only by law, including the main conditions and criteria. No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law no. 04/L-202 on Permit and License System,</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>6. In addition to service fees, a fee of 1% of the invoice for imported products is envisaged;</p> <p>7. The Registry of Licenses is missing or is incomplete.</p> <p>8. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>9. The rules for revocation and transfer of this permit are missing.</p>	<p>which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>5. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>6. Remove the tariff at the amount of 1% of the imported products.</p> <p>7. Establish/complete the Registry for</p>	<p>in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no legal basis and no justification is provided as to why it should be paid. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>Licenses with all the elements that the license contains.</p> <p>8. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>9. Change the permission category from license to permit;</p> <p>10. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	
Kosovo Medicines Agency	AKPP M10	License for import of precursors	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	<p>1. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>2. Some of the documents are not necessary to be requested from the party.</p> <p>3. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>5. In addition to service fees, a</p>	<p>1. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>2. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued</p>	<p>No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be restricted in time.</p> <p>Amendment of Administrative Instruction No. 06/2014, Determination of the List of Medicinal Products and Borderline Products, should be done in order that it contains the information according to paragraph 12 of Law No. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP.</p> <p>Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>fee of 1% of the imported products invoice value is envisaged; 6. The Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The rules for revocation and transfer of this permit are missing.</p>	<p>by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>4. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>5. Remove the tariff at the amount of 1% of the imported products.</p> <p>6. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>7. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>8. Change the</p>	<p>services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no legal basis and no justification is provided as to why it should be paid. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						permission category from license to permit; 9. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.	
Kosovo Medicines Agency	AKPP M11	License for import of psychotropics	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<p>1. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>2. Some of the documents are not necessary to be requested from the party.</p> <p>3. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>5. In addition to service fees, a fee of 1% of the imported products invoice value is envisaged;</p> <p>6. The Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to</p>	<p>1. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>2. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for</p>	<p>No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>Amendment of Administrative Instruction No. 06/2014, Determination of the List of Medicinal Products and Borderline Products, should be done in order that it contains the information according to paragraph 12 of Law No. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP.</p> <p>Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP.</p> <p>Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The removal of the 1% tariff for the imported products shall be done because the same has no</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>public health is improper.</p> <p>8. The rules for revocation and transfer of this permit are missing.</p>	<p>filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>4. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>5. Remove the tariff at the amount of 1% of the imported products.</p> <p>6. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>7. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>8. Change the permission category from license to permit;</p> <p>9. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>legal basis and no justification is provided as to why it should be paid.</p> <p>The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies.</p> <p>The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP.</p> <p>The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>
Kosovo Medicines Agency	AKPP M12	License for import of raw material - active	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA</p>	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 12 but not with a specific name;</p>	<p>1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, listing in an annex all prerequisite permits or licences needed to obtain an import license, along with the conditions and criteria for obtaining</p>	<p>The amendment of Law 04/L-190 on Medicinal Products and Medical Devices is needed in order to harmonize this law with Article 17, paragraph 1 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit and</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
y		substance		Director and Chief Executive	<p>2. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>3. There is no need for some of the documents to be requested from the party.</p> <p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>6. The Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The rules for revocation and transfer of this permit are missing.</p>	<p>those permits/licenses;</p> <p>2. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations and this permit to be given for an indefinite period by removing the validity period and the need for relicensing;</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>5. Amend the Law 04/L-190 on Medicinal</p>	<p>license can be defined only by law, including the main conditions and criteria. No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely restricted.</p> <p>The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law no. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>6. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>7. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>8. Change the permission category from license to permit;</p> <p>9. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>
Kosovo Medicines Agency	AKPP M13	License for import of raw material - auxiliary substance	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 12 but not with a specific name;</p> <p>2. The license is issued for a period of 3 months with the possibility of extension for 3 additional months (maximum 6 months). After the elapse of this</p>	<p>1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, listing in an annex all prerequisite permits or licences needed to obtain an import license, along with the conditions and criteria for obtaining those permits/licenses;</p> <p>2. Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations</p>	<p>The amendment of Law 04/L-190 on Medicinal Products and Medical Devices is needed in order to harmonize this law with Article 17, paragraph 1 of Law No. 04/L-202 on Permit and License System, which stipulates that a permit and license can be defined only by law, including the main conditions and criteria. No reason has been provided as to why the license term is 3 + 3 months, therefore there is no need for this type of license to be timely</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>period, a new application should be filed from the beginning in order to be equipped this license.</p> <p>3. There is no need for some of the documents to be requested from the party.</p> <p>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>6. The Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The rules for revocation and transfer of this permit are missing.</p>	<p>and this permit to be given for an indefinite period by removing the validity period and the need for relicensing; 3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices and the Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations, where only the information would be required and the same should be provided ex officio and not require documents such as: Copy of marketing authorization certificate, circulation license (retail or wholesale), business license issued by the competent authority, marketing authorization for medicinal products issued by the KMA, import authorization possessed by the importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards;</p> <p>4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>5. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through</p>	<p>restricted.</p> <p>The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law no. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<p>e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>6. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>7. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>8. Change the permission category from license to permit;</p> <p>9. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	reference to Law No. 04/L-202 on Permit and License System.
Kosovo Medicines Agency	AKPP M14	License for the production of medicinal products	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices refers to this type of permission in Article 10 as an authorization for production;</p> <p>2. The license is issued for a period of 5 years which is determined by a sub normative act and after the expiration of this period the relicensing must be done for which the same procedure as for licensing must be followed;</p> <p>3. The right to appeal is not fully regulated and is not in</p>	<p>1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices in order to issue this permit for an indefinite period of time by deleting the validity period and the need for relicensing;</p> <p>2. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>3. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove</p>	<p>Payment is the only reason why re-licensing is done. Therefore the need for re-licensing is unjustifiable and an unnecessary burden for the party.</p> <p>Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid</p>

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					<p>accordance with the LGAP.</p> <p>4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>5. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked;</p> <p>6. Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The rules for revocation and transfer of this permit are missing.</p>	<p>all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>4. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>5. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>6. Change the permission category from license to permit;</p> <p>7. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>
Kosovo Medicines Agency	AKPP M15	License for galenic laboratory	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	<p>1. Law No. 04/L-190 on Medicinal Products and Medical Devices mentions this type of permission in Article 10 as an authorization for production;</p> <p>2. The license is issued for a period of 5 years which is determined by a sub normative act and after the expiration of this period the relicensing must</p>	<p>1. Amend the Law 04/L-190 on Medicinal Products and Medical Devices in order to issue this permit for an indefinite period of time by deleting the validity period and the need for relicensing;</p> <p>2. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that</p>	<p>Payment is the only reason why re-licensing is done. Therefore the need for re-licensing is unjustifiable and an unnecessary burden for the party.</p> <p>Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and</p>

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					<p>be done for which the same procedure as for licensing must be followed;</p> <p>3. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>5. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked;</p> <p>6. Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The evaluation of the fulfillment of several criteria is done in the field by the senior officials of the KMA, and this is an obligatory phase of the procedure</p> <p>9. The rules for revocation and transfer of this permit are missing.</p>	<p>reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>3. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>4. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>5. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP;</p> <p>6. Change the permission category from license to permit.</p> <p>7. The assessment of compliance with the conditions and criteria to be done by completing an affidavit without senior KMA officials having the need to make a visit.</p> <p>8. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	<p>Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>
Kosov	AKPP	License for	Permit	KMA Licensing	1. The license is issued for a	1. This permit should be issued for an	Payment is the only reason why re-licensing is

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry of Medicines Agency	M16	operation with narcotics		Department; The license is signed by: KMA Director and Chief Executive	<p>period of 5 years, and after the expiration of this period the relicensing must be done for which the same procedure as for licensing must be followed;</p> <p>2. There is no need for some of the documents to be requested from the party.</p> <p>3. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>5. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked;</p> <p>6. Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The evaluation of the fulfillment of several criteria is done in the field by the senior officials of the KMA. This is a mandatory phase of the procedure and is charged for;</p> <p>9. The rules for revocation and</p>	<p>indefinite period of time in which case the validity period and the need for relicensing should be deleted;</p> <p>2. Amend the Administrative Instruction (MoH) No.11/2015 - Retailers for Medicinal Products and Medical Devices, where only the information would be required, and the same should be provided ex officio, rather than documents such as: Copy of work license (as wholesaler, retailer, or health institution), Copy of the work license of the responsible person, Copy of the identity card of the director and the responsible person, Certificate from the court regarding the criminal statute (for the director and the responsible person, original or notarized, not older than 6 months),</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>4. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by</p>	<p>done. Therefore the need for re-licensing is unjustifiable and an unnecessary burden for the party.</p> <p>The amendment of the Administrative Instruction (MoH) No.11/2015 on Retailers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law No. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is</p>

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					transfer of this permit are missing.	<p>the party should be refunded.</p> <p>5. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>6. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP.</p> <p>7. Change the permission category from license to permit.</p> <p>8. The assessment of compliance with the conditions and criteria to be done by completing an affidavit without senior KMA officials having the need to make a visit.</p> <p>9. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.
Kosovo Medicines Agency	AKPP M17	License for operation with precursors	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	<p>1. The license is issued for a period of 1 year, and after the elapse of this period the relicensing must be done for which the same procedure as for licensing must be followed;</p> <p>2. There is no need for some of the documents to be requested from the party.</p> <p>3. The right to appeal is not fully regulated and is not in accordance with the LGAP.</p> <p>4. The law envisages service fees</p>	<p>1. This permit should be issued for an indefinite period of time in which case the validity period and the need for relicensing should be deleted;</p> <p>2. Amend the Administrative Instruction (MoH) No.11/2015 - Retailers for Medicinal products and Medical Devices, where only the information would be required, and the same would be provided ex officio, rather than ask for documents such as: Court certificate for the criminal statute (for director and responsible person, original or notarized, not older than 6 months), copy of</p>	<p>Payment is the only reason why re-licensing is done. Therefore the need for re-licensing is unjustifiable and an unnecessary burden for the party.</p> <p>The amendment of the Administrative Instruction (MoH) No.11/2015 on Retailers for Medicinal Products and Medical Devices should be made in order that it contains the information provided in paragraph 12 of the Law No. 04/L-202 on Permit and License System, in order to harmonize it with Article 16 of Law No. 04/L-202 on Permit and License System but also with the principle of conducting an ex</p>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<p>for this type of permission, which is contrary to Article 12 of the LGAP.</p> <p>5. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked;</p> <p>6. Registry of Licenses is missing or is incomplete.</p> <p>7. The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health is improper.</p> <p>8. The evaluation of the fulfillment of several criteria is done in the field by the senior officials of the KMA. This is a mandatory phase of the procedure and is charged for;</p> <p>9. The rules for revocation and transfer of this permit are missing.</p>	<p>the identity card of the director and the responsible person.</p> <p>3. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of the complaint, the procedure, the body that reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with the LGAP.</p> <p>4. Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove all taxes for services and impose tariffs in accordance with Article 12 of the LGAP. The payment should be made at the end of the procedure and should also be done through e-banking, POS, etc. Accept any proof which confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded.</p> <p>5. Establish/complete the Registry of Licenses with all the elements contained by the license.</p> <p>6. Change the decision-making for this license and delegate the responsibility to the professional employee as provided in Article 26 of the LGAP. License signing should be made by the Head of the Unit, respectively the KMA responsible officer, appointed in accordance with the LGAP.</p> <p>7. Change the permission category from license to permit.</p> <p>8. The assessment of compliance with the conditions and criteria to be done by</p>	<p>officio procedure based on the LGAP. Amendment of Law 04/L-190 on Medicinal Products and Medical Devices should be made in order to regulate the right and appeals procedure which is missing. The amendment of Law 04/L-190 on Medicinal Products and Medical Devices should remove all taxes for services while the license fees should be determined pursuant to Article 12 of the LGAP. Additionally, it should envisage rules to enable the payment in the end, in order to avoid frequency and time loss for payment, and on the other hand not to envisage only one form of proof in order to prove the payment. The Registry of Licenses is necessary especially in case of loss or damage of a license in order to duplicate the same, but also to enable communication and exchange of information with other public bodies. The delegation of the decision-making competence, including the signing of a license, is a legal requirement based on the LGAP. The rules for revocation are necessary, even as a reference to Law No. 04/L-202 on Permit and License System.</p>

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						<p>completing an affidavit without senior KMA officials having the need to make a visit.</p> <p>9. Apply the rules on the revocation and transfer of this permit as provided by Law No. 04/L-202 on Permit and License System.</p>	
Kosovo Medicines Agency	AKPP M18	License for import of medicinal products for individual therapy	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	This license (permit) has no legal basis	Change the form of permission from 'license' to 'registration'	It is something excessive and unreasonable for the medicinal products of individual consumption to go through a standard licensing procedure. This type of license is single use license and does not apply for other cases.
Kosovo Medicines Agency	AKPP M19	License for export of medicinal products	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	This license (permit) contains no expressive legal basis in Law No. 04/L-190 for Medicinal Products and Medical Devices, whereas for its issuance are required documents which have already been issued by the KMA, such as. Marketing authorization, CPP Certificate (Certificate of Pharmaceutical Product), and manufacturing or import license.	Change the form of permission from 'license' to 'registration'.	This type of permission categorized as 'license' has no meaning and effect in protecting the public interest because it has already been achieved through three types of licenses which are issued by the KMA. The KMA may require for the exported medicinal products to be registered without having the need to be provided with a license.
Kosovo Medicines Agency	AKPP M20	License for the export of medical devices	Permit	<p>KMA Licensing Department;</p> <p>The license is signed by: KMA Director and Chief Executive</p>	This license (permit) has no expressive legal basis in Law No. 04/L-190 for Medicinal Products and Medical Devices, whereas for its issuance are required documents which have already been issued by the KMA, such as proof of import of the device, if the device is not a domestic	Change the form of permission from 'license' to 'registration'.	This type of permission which has been categorized as 'license' has no meaning and effect in protecting the public interest because it has already been achieved through three types of licenses which are issued by the KMA. The KMA may require for the exported medicinal products to be registered without having the need to be provided with a license.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					product.		