

**Republika e Kosovës Republika Kosova - Republic of Kosovo**  *Qeveria -Vlada-Government Zyra e Kryeministrit - Ured Premijera - Office of the Prime Minister Zyra Ligjore- Pravna Kancelarija- Legal Office* 

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)<sup>123</sup>

December 2021

<sup>&</sup>lt;sup>1</sup>This 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.

<sup>&</sup>lt;sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> 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	Type of	Responsible	Findings	Recommendations	Rationale
Ministry of	DSP1	permission 1. Licence for	permission Permit	authority	1 Deregraphs 1 and 2 of Article 20	1 Amond in ontiraty law No.	1 Daragraph 1 41 of Article 2 of
Ministry of	DSP1		Permit	Ministry of Internal	1. Paragraphs 1 and 2 of Article 29		1. Paragraph 1.41 of Article 2 of
Internal Affairs		manufacturing		Affairs, Department	of Law No. 04/L-022 on Civil Use of	04/L-022 on Civil Use of	Law No. 04/L-022 on Civil Use of
Affairs		explosives and		of Public Safety	Explosives stipulate that the general	Explosives, specifically	
		fireworks			license is issued for manufacturing,	paragraph 1 of Article 20	license is the authorization
		2. Licence for			import/export/ transfer and use.	thereof, in order to abolish the	issued from the competent body
		import, export,			These three licenses are issued	obligation of legal persons to	
		transit and transfer			parallel to the business registration	obtain a general license for the	holder is authorized to be
		of explosives and			procedure with the KBRA. Upon	manufacturing, import, export,	engaged in a special type of
		fireworks			obtaining these licenses, companies	transit, transfer and use of	business or other activity in
		3. Licence for use			are registered as entities for the	fireworks and explosives,	compliance with terms
		of explosives and			manufacturing, import, export,	requiring instead of obtaining a	prescribed in the license
		fireworks			transit, transfer and use of	license general registration at	according to this law. This
					fireworks and explosives, but they	the Ministry of Infrastructure	
					are not granted the right to exercise	which would serve for all three	procedure required for business
					the specified activity upon	activities (manufacturing,	registration with KBRA. So, in
					obtaining the general license.	import/export/transfer and	addition to the application for
						use).	business registration with KBRA,
					2. Paragraph 9 of Article 29 of Law		the legal person is obliged to be
					No. 04/L-022 on Civil Use of	2. Amend Articles 31, 32, 33, 38	licensed (which is essentially a
					Explosives specifies that licenses are	and 39 of Law No. 04/L-022 on	<b>.</b> ,
					valid for a period of 5 years, which	Civil Use of Explosives in order	MIA. And with the licensing of
					implies that companies should be	to abolish the obligation to	the company, the legal person
					re-licensed after five years.	obtain a license by legal persons	cannot start exercising its
						and to require their registration	activity again since it requires
					3. The Minister's Decision No.	according to Article 7 of Law No.	special permits, so the practical
					154/2016 on Setting of Fees	04/L-202 on Permit and License	relevance of licenses is the same
					specifies that the cost for obtaining	System.	as registering a business with
					each of these licenses is EUR 500. In		KBRA. Therefore, for the sake of
					other words, a company has to pay	3. Amend paragraph 9 of Article	public safety and the state need
					a fee of EUR 500 three times for	29 of Law No. 04/L-022 on Civil	to have knowledge about the
					each license, and they should be	Use of Explosives in order to	existence of companies that
					licensed every 5 years.	determine the obligation of	exercise these activities, it is

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry	Ref. No.			•	<ul> <li>Findings</li> <li>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.</li> <li>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).</li> </ul>	Recommendationscompanies to notify the MIAevery five years that theycontinue to exercise the sameactivity.4. Propose to the Ministry thatthe fee of EUR 500 applied forthis procedure be calculatedwithin the cost of thisregistration, to ensurecompliance with Article 18 ofthe Law on Permit and LicenseSystem.5. Amend AdministrativeInstruction No. 04/2013 onCriteria and Procedures forLicenses and Permits andAdministrative Instruction (MIA)No. 07/2013 on UN HazardsClassification and CompatibilityGroups in the respectivesections where the licensingobligation is determined so thatthe registration and notificationobligation is determined.	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. 2. Since by registration the legal person is already part of the register of the MIA, for security purposes, based on Article 6 of
					<ul><li>(Copy).</li><li>6. The appeal procedure is not regulated in accordance with the</li></ul>	<ul><li>obligation is determined.</li><li>6. Amend Administrative</li></ul>	purposes, based on Article 6 of the Law on Permit and License System, the legal person may notify the competent authority
					provisions of the LGAP.	Instruction No. 04/2013 on Criteria and Procedures for Licenses and Permits and Administrative Instruction (MIA)	that it continues to exercise the same activity every 5 years. The same cannot be registered for the second time since it is
						No. 07/2013 on UN Hazards	

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>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).</li> <li>7. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</li> </ul>	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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							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. 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.
Ministry of Internal Affairs	DSP2	<ol> <li>Permit for import, export, transit or transfer of explosives and fireworks;</li> <li>Permit for retail shop to sell fireworks;</li> <li>Permit for</li> </ol>	Permit	Ministry of Internal Affairs, Department of Public Safety	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.	04/L-022 on Civil Use of Explosives, so that explosives and fireworks are regulated as separate categories.	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

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

authorized persons and Certificates submit documents such as: Copy which regulates t of qualified persons; for Permit for of storage permit and Copy of and deadlines for	Ministry	Rationale
documents such as: Certificate of professional qualification (relevant experience) (Copy), Certificate of authorized persons (Copy), Identity card. 3. The appeals procedure is not regulated in accordance with the provisions of the LGAP. browners authorized persons (Copy), Certificate of authorized persons (Copy), Certificate	VIIIISTY	they are integral to each other. 4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>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);</li> <li>Permit for use (blast permit), the legal person is obliged to submit documents such as: Certificate of professional qualification (relevant experience) (Copy), Location of Safety Plan and Risk Assessment. (Copy);</li> <li>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.</li> <li>The appeal procedure should be regulated in accordance with the provisions of the LGAP.</li> </ul>	
Ministry of Internal Affairs	DSP3	Authorization for commencing operations of Private Security Company • Authorization for commencing operations of	Permit	Ministry of Internal Affairs, Department of Public Safety	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	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	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

Ministry Re	f. No. Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry Re	f. No.Name of permissionBasic Security ServicesAuthorization for commencing 	permission pr	Responsible authority	Findings16.11.2016 and Decision No.394/2017 dated 15.12.2017foresees the fee of EUR 20 forobtaining the Authorization forcommencing operations of a privatesecurity company, which in essenceis the notification of MIA on clientsof the security company, so that theMIA knows who the clients of thecompany are.2. Decision No. 12/20 on Setting ofFees, dated 16.01.2020 specifies inAnnex 2 five (5) types ofauthorization by service, with feesranging from EUR 5 to EUR 20.This fee paid upon obtaining theauthorization for commencingoperations of Private SecurityCompany is in essence a notice tothe MIA on the clients of thesecurity company which ensuresthe MIA is informed on thecompany's clients. The fees due foreach authorization are as follows:• Authorization forcommencing operations of BasicSecurity Services (EUR 10)	RecommendationsDecision of the Minister No.154/2016 on Setting of Feesdated 30.05.2016, abrogated byDecision No.328/2016 dated16.11.2016 - and by DecisionNo.394/2017 dated 15.12.2017,in order to abolish the foreseenfee of of EUR 20 for notification.2. Amend Decision No.12/20 onSetting of Fees, dated16.01.2020 Annex 2, to abolishthe foreseen fee of EUR 5-20 fornotification purposes.3. Change the practice of theMIA for requesting a copy of thelicense of the company toperform the relevant services.	Authorization, then its name is changed to Notice as it serves the same purpose. 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. 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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					Authorization for commencing operations of CIT Services (EUR 20)		
					Authorization for commencing operations of Electronic Property Surveillance (EUR 5)		
					<ul> <li>Authorization for commencing operations of Security Services of Public Gatherings (EUR 5)</li> </ul>		
					• Authorization for appointment of CPOs (EUR 5)		
					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		
Ministry of Internal Affairs	DSP4	Certification of Control Center	/	Ministry of Internal Affairs, Department of Public Safety	services (Copy) 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	the Law on Private Security Services and merge them. 2. Such a certificate should be removed from the register of	company obtains a license for the provision of specialized
					services, and property electronic surveillance services. At the moment of receiving the license	Setting of Fees dated	2. The abolition of the payment for obtaining this certificate,

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<ul> <li>from the competent body, the company can start providing the service immediately.</li> <li>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.</li> </ul>	in order to abolish the requirement to pay the fee of EUR 50 for obtaining this certificate.	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.
Ministry of Internal Affairs	DSP5	<ol> <li>License for Basic Security Worker;</li> <li>License for Close Protection Operative;</li> <li>License for CIT Guard;</li> <li>License for dog- handler;</li> <li>License for dog- handler;</li> <li>License for Electronic Surveillance Operator;</li> <li>License for Security Manager/Duty Officer</li> </ol>		Ministry of Internal Affairs, Department of Public Safety	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.	<ol> <li>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:         <ol> <li>License for Basic Security Worker;</li> <li>License for Close Protection Operative;</li> <li>License for ClT Guard;</li> <li>License for Electronic Surveillance Operator;</li> <li>License for Security Manager/Duty Officer</li> </ol> </li> </ol>	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.
Ministry of Internal Affairs	DSP6	Official identification cards	/	Ministry of Internal Affairs, Department of Public Safety	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.	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	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.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<ol> <li>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.</li> <li>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</li> </ol>	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	<ul> <li>personnel.</li> <li>1. Law No. 04/L-004 on Private Security Services in Article 10, paragraph 1.2 provides for the License for Close Protection Services.</li> <li>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.</li> </ul>	<ul> <li>Private Security Services, Article</li> <li>10, paragraph</li> <li>1.2 which</li> <li>foresees the License for Close</li> <li>Protection Services, so that it</li> <li>foresees the Permit for Close</li> <li>Protection Services.</li> </ul> 2. Amend Administrative	<ul> <li>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 is issued for professional activities to natural persons.</li> <li>2. The abolition of the obligation to submit a copy of the relevant</li> </ul>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
Ministry	Ref. No.			-	Findings         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.         4. The appeal procedure is not         regulated in accordance with the         provisions of the LGAP.	Recommendationscopy of the license for the manager of basic security services (Copy) and the certificate of the Control Center, 	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. 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.

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure including the procedure
Ministry of Internal Affairs	DSP8	License for Cash in- Transit services (CIT)	Permit	Ministry of Internal Affairs, Department of Public Safety	<ol> <li>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).</li> <li>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.</li> <li>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.</li> </ol>	<ol> <li>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.</li> <li>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.</li> </ol>	<ul> <li>concerned.</li> <li>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.</li> <li>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,</li> </ul>
					4. The appeal procedure is not	3. Propose to the Ministry to	

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					regulated in accordance with the provisions of the LGAP.	<ul> <li>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.</li> <li>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).</li> <li>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</li> </ul>	them. Such practice creates a great administrative burden for businesses and is completely meaningless. 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. 4. LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure
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	services is changed to Permit for basic security services since it is issued to legal persons and

Ministry R	 Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
				<ol> <li>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,</li> <li>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.</li> <li>The appeal procedure is not regulated in accordance with the provisions of the LGAP.</li> </ol>	<ul> <li>the same provides for the Permit for basic security services.</li> <li>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.</li> <li>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.</li> <li>4. The appeal procedure should be regulated in accordance with the LGAP.</li> </ul>	Permit and License System to be classified as a permit, while the license is issued for professional activities to natural persons. 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. 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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							renewing it is in accordance with the law.
							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	DSP10	License for Electronic Property Surveillance Services	Permit	Ministry of Internal Affairs, Department of Public Safety	<ol> <li>Law No. 04/L-004 on Private Security Services foresees in Article 10, paragraph 1.4 the License for electronic property surveillance services.</li> <li>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</li> <li>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.</li> </ol>	<ol> <li>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.</li> <li>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.</li> <li>Propose to the Ministry to</li> </ol>	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

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

must submit the following documents at the time of application: (i) Copies of 15 licenses of basic security workers; (ii) Certificate of Control Center2. Amend Administrative Instruction No. 27/2011-MIA on Licensing Procedures which stipulates that the legal person submit the following documents at the time of application: i) Copy of 15 iscenses of basic security workers; (ii) the license and EUR 250 for regulated in accordance with the provisions of the LGAP.2. Amend Administrative Instruction No. 27/2011-MIA on submit the following documents at the time of application: i) copy of 15 iscenses of basic security workers; (ii) the certificate of the Control Center, which are issued by the MIA is recommended because there is the license and EUR 250 for renewing it.2. Anolition of the obligation to submit the following documents at the time of application: i) copy of 15 workers, (ii) the certificate of the Control Center. regulated in accordance with the provisions of the LGAP.2. Anolition of the obligation to submit the control Center.4. The appeal procedure is in the provisions of the LGAP.3. Propose to the Ministry to callute the fee of EUR 500 for creates a great administrative cost of the license, to ensure cost of the license, to ensure cost of the license, to ensure cost of the lesnes, to ensure authority may charge for a authority may charge for a authority may charge for a authority may charge for a securities to the analysis whether the ef of EUR S00 for obtaining a license and EUR 250 for renewing it, as well a securit accordance with the provisions of the LGAP.3. The fee that a competent analysis whether the ef of EUR S00 for obtaining a license and EUR 250 for renewing it, as well a scuradance with the a
4. LGAP is a framework law

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

Ministry	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
				of the contract manager (Verified copy). 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 4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.	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). 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. 4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.	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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
							<ul> <li>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.</li> <li>4. LGAP is a framework law which regulates the procedure and doadlings for filing and</li> </ul>
							and deadlines for filing and handling complaints in any administrative procedure including the procedure concerned.
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	<ol> <li>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.</li> <li>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</li> </ol>	<ol> <li>Amend Law No. 04/L-004 on Private Security Services, Article</li> <li>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.</li> <li>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</li> </ol>	<ol> <li>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.</li> <li>Abolition of the obligation to submit: (i) Request for background checks for the applicant entity, founders,</li> </ol>

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

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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					EUR 250 for renewing it. 4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.	<ul> <li>Number of certified and registered workers (Copy), (iii) Certificates of construction materials used (Copy).</li> <li>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.</li> <li>4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.</li> </ul>	<ul><li>creates a great administrative burden for businesses and is completely meaningless.</li><li>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</li></ul>

Ministry	Ref. No.	Name of	Type of	Responsible	Findings	Recommendations	Rationale
	D 4 4 4 5 4	permission	permission	authority			
Ministry of	DAME1	Authorization on	Profession	Ministry of Internal	1. Paragraph 5 of Article 19 of Law	1. Amend Article 19, paragraph	1. These authorizations meet all
Internal		requirements for	al license	Affairs, EMA	No. 04/L-012 on Fire Protection	5, of the Law on Private Security	the requirements of a
Affairs		fire protection			states that "Control of regularity	Services, So that it lays down	professional license under
		advancement			and servicing of apparatus may	the need for professional	Article 9 of the Law on Permit
		work, with nine			be practiced by authorized persons	licensing of natural persons	and License System. This law
		categories of			who are technically and	applicable to all categories,	does not recognize the term
		authorizations			professionally trained, according	instead of their authorization.	authorization.
		issued:			to the authorization of the	Add this professional license in	
					Ministry-Agency. While	the register.	2. The proposal to merge the 9
		- Authorization for			Administrative Instruction No.		authorizations aims at reducing
		carrying out			25/2012 on requirements for fire	2. Propose to the Ministry that	the administrative burden and is
		studies on fire			protection advancement work	the fee of 9 x EUR 250 to obtain	based on their redundancy.
		protection			specifies 9 categories in Article 1	this license be calculated within	
		organization				the cost for obtainin it, to	3. The fee that a competent
					2. For these authorizations that are	ensure compliance with Article	authority may charge for a
		- Authorization for			already issued by the MIA, the	18 of the Law on Permit and	permission shall not exceed the
		carrying out			parties pay the amount of EUR 250	License System. This calculation	amount required to cover the
		analyzes of the			for each.	can be done by the project.	cost that the competent
		existing fire					authority incurs in administering
		protection					the permission (Article 18 of the
		situation					Law on Permit and License System). The project can assist
		- Authorization for					with this calculation, as well as
		the development					with the analysis if the fee of $9 \times 10^{-10}$
		of fire protection					EUR 250 for a license is in
		improvement and					accordance with the law.
		advancement					accordance with the law.
		programs					
		Programs					
		- Authorization for					
		carrying out					
		analyzes of					
		dangerous areas					
		and the definition					

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

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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
		measures			obtaining the consent and EUR 50 for the field visit. 4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.	cost of this consent, to ensure compliance with Article 18 of the Law on Licenses. This	<ol> <li>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.</li> <li>LGAP is a framework law which regulates the procedure and deadlines for filing and handling complaints in any administrative procedure</li> </ol>
Ministry of Internal Affairs	DAME4	Certificate for passing the professional fire protection exam	Profession al license	Ministry of Internal Affairs, EMA	<ol> <li>Law No. 04/L-012 on Fire Protection does not explicitly provide for this certificate.</li> <li>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</li> </ol>	Certificate for passing the professional fire protection exam to License for fire protection. 2. Amend Administrative Instruction (MIA) No. 16/2017 on Preparing Candidates for Passing the Professional Exam in the Area of Fire Protection in	<ul> <li>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.</li> <li>2. Abolition of the obligation to submit the following</li> </ul>

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					<ul> <li>card (Copy), (ii) Birth certificate (Copy), (iii) Proof of special training (Copy).</li> <li>3. A fee of EUR 150 must be paid for obtaining this license.</li> <li>4. The appeal procedure is not regulated in accordance with the provisions of the LGAP.</li> </ul>	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). 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. 4. The appeal procedure should be regulated in accordance with the provisions of the LGAP.	(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.

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

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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					Instruction (MI)	Ministry that the	this purpose, control
					No. 20/2017 on	fee of EUR 100 -	mechanisms should be
					Licensing of	500 for obtaining	developed that ensure that
					Driving Schools.	this permit be	the entity that holds a
						calculated within its	permit continues to meet
					4. The license is	cost, to ensure	the legal criteria for the
					valid only for five	compliance with	permit it holds. In this way,
					(5) years,	Article 18 of the	the administrative and
					obliging the	Law on Licenses.	financial burden of the
					driving schools	This calculation can	driving school and the
					to go through	be done by the	relevant institutional officials
					the same	project.	is alleviated. Further, the
					procedure every		applicable fee for obtaining a
					5 years, filling in		permit is abolished in
					the forms for		accordance with the
					each category		provision of Article 18 of the
					and making the		Law on Permits and Licenses.
					payment of the		
					procedure for		The fee that a competent
					each category.		authority may charge for a
							permission shall not exceed
					4. The fee paid		the amount required to
					for obtaining this		cover the cost that the
					license ranges		competent authority incurs
					from EUR 100 to		in administering the
					EUR 500.		permission (Article 18 of the
							Law on Permit and License
							System). The project can
							assist with this calculation.
Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
----------------	----------	---------------------	----------------------	-----------------------	---------------------	-----------------------	-----------------------------------
Ministry of	DA2	Licence for	Professional Licence	MESPI - Department of	1. Law No. 05/L-	1. Amend Article	The relicensing requirement
Environment,		professional		Vehicles	064 on Driving	10, paragraph 2, of	is unnecessary considering
Spatial		lecturer in driving			License	Law No. 05/L-064	the fact that the applicant,
Planning and		school			stipulates in	on Driving License	following licensing and
Infrastructure					Article 10,	so that it is	commencement of activity
					paragraph 2,	determined that	of professional lecturer,
					that the license	the validity of the	during the 5-year period
					for professional	license is	trains hundreds of
					lecturer is issued	permanent and not	candidates who then receive
					with a validity of	5 years.	a permanent driving license.
					five (5) years,		Therefore, the requirement
					with the	2. Change the	that he/she undergo the
					possibility of	practice of	same examinations and
					renewal.	requiring	administrative procedures
						submission of the	every five (5) years is difficult
					2. The	Certificate for basic	to understand and
					documents	training during	objectively unnecessary
					required to	applications for a	considering the five (5) year
					apply include the	license.	expertise that he/she
					Certificate for		acquires following licensing.
					basic training,	3. Amend Article 31	In case of abolition of the
					while the law	of AI No. 04/2018	obligation to renew the
					recognizes this	and regulate the	license and recognition of
					only as a	appeal procedure in	the permanent validity of the
					criterion.	accordance with	license for professional
						the LGAP.	lecturer, the fee of EUR 50
					3. Article 31 of Al		for renewing the candidate's
					No. 04/2018	4. Propose to the	license is avoided.
					regulates the	Ministry that the	
					appeal	fee of EUR 250 paid	2. The Certificate for basic
					procedure,	for basic training	training is issued by MESPI or
					which is not in	and the fee of EUR	any licensed operator of the
					accordance with	100 for obtaining	Ministry. The applicant
					the LGAP.	this license be	should be spared the
						calculated within	additional administrative

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

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

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

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

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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					license, the applicant pays for the theoretical and practical exam, as well as additional fees of EUR 100 for licensing and relicensing each.		<ul> <li>burden for submitting duplicate documents issued by the Ministry itself.</li> <li>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</li> </ul>
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 DrivingLicensestipulates inArticle 21 thatentitiesauthorized byrespectiveMinistry ofTransport asprovided inArticle 121 ofthis Law shallhave 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.	licensing. 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

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

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

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

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

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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					3. When	requirement that	whether the fee of EUR 200
					applying for this	the applicant pay	reflects the costs incurred by
					license, the	the fee of EUR 10	the authority during the
					applicant pays	upon application.	licensing process.
					the fee of EUR		
					200.	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.	
Ministry of	DTT4	Licence for	Permit	Ministry of Infrastructure,	1. Law No. 04/L-	1. Amend Law No.	1. Based on Law No. 04/L-
Environment,		terminals		Department of Road Transport	183 on Land	04/L-183 on Land	202 on Permit and License
Spatial					Transport of	Transport of	System, the professional
Planning and					Dangerous	Dangerous Goods,	license is issued to natural
Infrastructure					Goods foresees	which foresees in	persons, while the permit is
					in Article 7 the	Article 7 a License	issued to legal persons as in
					license for	for terminals to	this case. Therefore the
					terminals.	foresee instead a	proposed amendment is
						Permit for	based on Articles 8 and 9 of
					2. Administrative	terminals.	this Law.
					Instruction No.		
					08/2015 on	2. Amend Article 8	2. Abolition of the
					Licensing of	of Administrative	requirement to pay upon
					Terminals for	Instruction No.	application is made in
					Goods foresees	08/2015 on	accordance with Article 18 of

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

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

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

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

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

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

Ministry	Ref. No.	Name of permission	Type of permission	Responsible authority	Findings	Recommendations	Rationale
					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. 3. When applying for this permit, the applicant pays a fee of EUR 100.	documents when applying: License A, B or D; Bus logbook, valid technical control, bus insurance and certificate according to license A, B and D. 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	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,	project.1.AmendAdministrativeInstructionInstructionNo.06/2015onissuance of permitsfortheperformanceofregularinternationalinternationalroadtransportof	<ol> <li>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.</li> <li>Abolition of the requirement to submit notarized documents upon</li> </ol>

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

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	<ol> <li>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.</li> <li>Administrative Instruction No. 09/2013 on the routes network and timetables of interurban</li> </ol>	1.AmendAdministrativeInstructionNo.09/2013ontheroutes network andtimetablesofinterurbanpassengertransportbybusand AI No.06/2016onamendmentthereof,Article	<ol> <li>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.</li> <li>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.</li> <li>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</li> </ol>

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

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

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

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

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

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

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

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

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

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 goodsnecessary only for additional tructs 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).
Ministry of	DTT16	Permit for	Permit	Ministry of Infrastructure,	1. Administrative	1. Amend Article 9	<ul> <li>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.</li> <li>1. The short time provided</li> </ul>
Environment, Spatial Planning and Infrastructure		extraordinary transport of goods		Department of Road Management	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	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	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
					1.1 of Article 7 of Administrative Instruction No.	one (1) month.	validity time. 2. Abolition of the

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

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

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

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

MinistRef.Name ofType ofResponsibleFindingsryNo.permissionpermisauthoritysion	Recommendations	Rationale
ber of A of physiother apists Commission; Chambers of Healthcare Hee Professionals, Article 9, all paragraph 1.3, regulates only chamber for licensing, relicensing and 2. revocation but not this type of Profession but not this type of Profession but not this type of Professions. Some of the documents do not need to be requested from No on the party. 3. The appeal procedure is missing. 3. The appeal procedure is missing. 3. Professional definition of the party. 3. The appeal procedure is missing. 3. Professional definition of the the party. 3. The appeal procedure is missing. 4. Inappropriate and restricted payment method. 5. This Chamber delivers almost all licensing services, as well as other services electronically 4. through its website https://oftk- Ad ks.org/ which is sufficiently user friendly. 6. of the documents is bar of the services almost appeal procedure is the service of the services	<ol> <li>Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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).</li> <li>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.</li> <li>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.</li> <li>The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li> </ol>	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. 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. Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing. 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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						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.	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.
						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).	
Cham ber of Physio therap ists of Kosov o	OFK1- B	Relicensing of physiother apists	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	<ol> <li>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.</li> <li>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.</li> <li>OFKT1-A license does not need to be</li> </ol>	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-202 on Permit and License System).

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>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.</li> <li>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.</li> <li>5. These changes can be made by amending Regulation No. 01/20120 on Procedures and</li> </ul>	
Cham ber of Physio therap ists of Kosov o	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	<ul> <li>Criteria for Membership in OFK</li> <li>1. Require the submission of only a request with minimum data to make known the fact of loss and damage of the license.</li> <li>2. Other data are or should be in the register of licenses kept by the chamber.</li> <li>3. The duplicate copy should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li> </ul>	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.
Kosov o Doctor s Cham ber	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	<ol> <li>Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>Amend Regulation No. 01/2020 on</li> </ol>	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.

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
(ОМК)			sion	the Chair of the Chamber	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.	<ul> <li>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.</li> <li>3. Amend Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians which establishes the right to appeal and the deadline for submitting the appeal and deciding on the appeal.</li> </ul>	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. Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.
						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.	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.
						<ul> <li>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li> <li>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</li> </ul>	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	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.	
Kosov o Doctor s Cham ber (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	<ol> <li>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.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>These changes can be made by amending Regulation No. 04/2020 on Registration,</li> </ol>	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						Licensing, and Relicensing of Physicians.	
Kosov o Doctor s Cham ber (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> <li>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.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure is missing.</li> <li>Inappropriate and restricted payment method.</li> </ol>		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. 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. Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing. 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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						of the Chamber or by a Chamber official authorized for this purpose. 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.	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.
Kosov o Doctor s Cham ber (OMK)	OMK2- B	Relicensing of specialists and sub- specialists (specialist 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 license OMK2-A	<ol> <li>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.</li> <li>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.</li> <li>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.</li> <li>Amend Regulation No. 04/2020 on</li> </ol>	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).

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Kosov o Doctor s Cham ber (OMK)	ОМКЗ	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	<ol> <li>Law No. 04/L-150 on Chambers of Healthcare Professionals does not regulate this type of permit anywhere.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure is missing.</li> <li>Inappropriate and restricted payment method.</li> <li>The deadline for issuing the license is missing.</li> </ol>	<ul> <li>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.</li> <li>6. These changes can be made by amending Regulation No. 04/2020 on Registration, Licensing, and Relicensing of Physicians.</li> <li>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> <li>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 the deadline for submitting the appeal and deciding on the appeal.</li> <li>4. Amend Decision No. 02/2020 on Administrative Fees for OMK services so that</li> </ul>	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
						payment is made at the end of the procedure and is also made through e- banking, POS, etc. Accept any proof of	procedure of appeal which is completely missing.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>payment.</li> <li>5. Establish the deadline on procedure implementation and decision making for this type of license.</li> <li>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).</li> </ul>	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. 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.
Kosov o Doctor s Cham ber (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> <li>Require only one request with minimum data to make known the fact of loss or damage of the license.</li> <li>Other data are or should be in the register of licenses kept by the chamber.</li> <li>The duplicate copy should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li> </ol>	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.
Cham ber 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,

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
acists				License is signed	paragraph 1.3, regulates only	chambers.	of Law No. 04/L-202 on Permit and License
of Kosov				by the Chair of the Commission and	the competence of the chamber for licensing, relicensing and	2. Amend Regulation No. 08/2019 on	System, according to which a permit and license can be determined only by law.
NUSUV O				the Chair of the	revocation but not this type of	Licensing and Relicensing of Pharmacists to	can be determined only by law.
(OFK)				Chamber	permit.	require only information, to be submitted ex	Amendment of Regulation 08/2019 on Licensing
(,					2. Some of the documents do	officio, without needing to submit	and Relicensing of Pharmacists should be made
					not need to be requested from	documents such as: Copy of ID card,	to harmonize it with Article 16 of Law No. 04/L-
					the party.	Notarized Certificate of professional exam or	202 on Permit and License System, but also to
					3. The appeal procedure in the	specialist exam, Membership identification	ensure compliance with the principle of
					case of licensing is missing,	card.	conducting the procedure ex officio according to
					while for relicensing it is not	2 Amount Description No. 00/2010 and	the LGAP. The change from a registered
					complete. 4. Inappropriate and restricted	3. Amend Regulation No. 08/2019 on Licensing and Relicensing of Pharmacists	document to a request, such as requesting personal data instead of a copy of the identity
					payment method.	which establishes the right to appeal, the	card, is done in order to enable electronic
					payment method.	procedure, the body that reviews the appeal	communication, including the interconnection
						and the deadline for filing a complaint and	of electronic systems.
						deciding on the complaint.	
							Further, the amendment of the regulation
						4. Amend Decision No. 08/ on Administrative	should be made to regulate the right to and
						Fees for OFK services so that payment is	procedure of appeal which is completely
						made at the end of the procedure and is also	missing.
						made through e-banking, POS, etc.	Amendment of Decision No. 08/2019 on
						5. The license should be signed by the Chair	Administrative Fees for OFK services should be
						of the Chamber or by a Chamber official	done to enable payment in the end to avoid
						authorized for this purpose.	frequency of and loss of time for payment as
							well as to abolish the restriction of only one
						6. In cases when the submission of some	form of payment proof accepted.
						documents is necessary, not to request a	
						notarized copy of them; e.g. 'Notarized	The fee and any other payment should be in
						certificate of professional exam or specialist	accordance with Article 18 of Law No. 04/L-202
						exam' required. Notarization is not required	on Permit and License System and should not
						as this document is issued by the Ministry of	exceed the amount required to cover the cost

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>Health itself. This applies to all licenses issued by OFK.</li> <li>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).</li> </ul>	that the competent authority incurs in administering the permission.
Cham ber of Pharm acists of Kosov o (OFK)	OFK1- B	Relicensing of pharmacist s	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	<ol> <li>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.</li> <li>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.</li> <li>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.</li> </ol>	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).

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Cham ber of Pharm acists of Kosov o (OFK)	OFK2	Permit for profession al scientific research	Permit	Ethical Commission; Permit is signed by the Chair of the Ethical Commission	<ol> <li>Law No. 04/L-150 on Chambers of Healthcare Professionals does not regulate this type of permit anywhere.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure is missing.</li> <li>Inappropriate and restricted payment method.</li> <li>The deadline for issuing the license is missing.</li> </ol>	<ul> <li>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.</li> <li>5. These changes can be made by amending Regulation No. 08/2019 on Licensing and Relicensing of Pharmacists.</li> <li>6. Abolish the relicensing fee of EUR 100.</li> <li>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> <li>3. Amend Regulation No. 12/2020 on the Scope and Competencies of the Ethical commission 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.</li> <li>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.</li> </ul>	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 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
						4. Amend Decision to supplement the	Further, the amendment of the regulation

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>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.</li> <li>5. Establish the deadline for procedure implementation and decision making for this type of license.</li> <li>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).</li> </ul>	procedure of appeal which is completely missing. 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. 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.
Cham ber of Pharm acists of Kosov o (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> <li>Require only one request with minimum data to make known the fact of loss or damage of the license.</li> <li>Other data are or should be in the register of licenses kept by the chamber.</li> <li>The duplicate copy should be signed by the Chair of the Chamber or by a Chamber</li> </ol>	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						official authorized for this purpose.	
Cham ber of Dentis ts of Kosov o (OSK)	OSK1- A	General licensing (of doctors of stomatolog y)	Licence	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<ol> <li>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.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure in the case of licensing is missing.</li> <li>Inappropriate and restricted payment method.</li> </ol>	<ol> <li>Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li> <li>Licensing fee of EUR 100 may not be in</li> </ol>	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. 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. Further, the amendment of the regulation is needed to regulate the right to and procedure of appeal which is completely missing. 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. The fee and any other payment should be in accordance with Article 18 of Law No. 04/L-202

Minist ry	Ref. No.	Name of permission	Type of permis sion	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.
Cham ber of Dentis ts of Kosov o (OSK)	OSK1- B	General relicensing (of doctors of stomatolog y)	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> <li>The OSK1-B license should be issued for an indefinite term.</li> <li>The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</li> <li>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.</li> <li>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.</li> <li>Amend Regulation No. 12/2019 on Registration, Licensing, and Relicensing of</li> </ol>	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).

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>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.</li> <li>6. These changes can be made by amending Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists.</li> <li>7. Abolish relicensing fee (EUR 100).</li> </ul>	
Cham ber of Dentis ts of Kosov o (OSK)	OSK2- A	Specialist licensing (of specialists of stomatolog y)	License	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<ol> <li>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.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure in the case of licensing is missing.</li> <li>Inappropriate and restricted payment method.</li> </ol>	<ol> <li>Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> <li>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.</li> </ol>	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. 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 Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>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.</li> <li>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li> <li>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</li> </ul>	missing. 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. 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.
Cham ber of Dentis ts of Kosov o (OSK)	OSK2- B	Specialist relicensing (of specialists of stomatolog y)	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	Same as license OSK1-A	<ul> <li>World Bank can provide assistance with this).</li> <li>1. The OSK2-license should be issued for an indefinite term.</li> <li>2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</li> <li>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.</li> </ul>	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).

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
				Licensing Commission and the Chair of the Chamber		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.	
						<ul> <li>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.</li> <li>6. These changes can be made by amending Regulation No. 12/2019 on Registration, Licensing, and Relicensing of Dentists.</li> </ul>	
Cham ber of Dentis ts of Kosov o (OSK)	OSK3	Permit for scientific bio- medical research	Permit	Ethical Commission; Permit is signed by the Chair of the Ethical Commission	<ol> <li>Law No. 04/L-150 on Chambers of Healthcare Professionals does not regulate this type of permit.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure is missing.</li> <li>Inappropriate and restricted payment method.</li> <li>The deadline for issuing the</li> </ol>	<ul> <li>7. Abolish the relicensing fee (EUR 100).</li> <li>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> </ul>	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 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					license is missing	<ol> <li>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.</li> <li>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.</li> </ol>	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. Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing.
						<ul> <li>5. Establish the deadline for procedure implementation and decision making for this type of license.</li> <li>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).</li> </ul>	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. 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.
Cham	OSK4	License	Licence	Licensing	This license should not be	1. Require only a request with minimum data	There is no need and no argument for
ber of		duplicate		Commission;	included in the register as it is	to make known the fact of loss or damage of	implementing a procedure and convening the

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Dentis ts of Kosov o (OSK)		(license copy)		License is signed by the Chair of the Commission and the Chair of the Chamber	not a new license	<ul><li>the license.</li><li>2. Other data are or should be in the register of licenses kept by the chamber.</li><li>3. The duplicate copy should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li></ul>	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.
Kosov o Cham ber 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	<ol> <li>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.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure in the case of licensing is missing.</li> <li>The method of payment is more convenient but still restricted.</li> </ol>	<ol> <li>Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>The license should be signed by the Chair of the Chamber or by a Chamber official</li> </ol>	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 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. Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing. Amendment of Decision on Administrative Fees for OIK services should be done to enable

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						authorized for this purpose.	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.
							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.
Kosov o Cham	OIK1-B	Relicensing with secondary	License	Licensing Commission;	Same as license OIK1-A	1. The OIK1-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 the whole purpose of relicensing is to ascertain
ber of Nurses (OIK)		school		License is signed by the Chair of the Licensing Commission and the Chair of the Chamber		<ol> <li>2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</li> <li>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.</li> <li>4. 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,</li> </ol>	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).
						and the examination process can be continued to prove that the professional qualifications have been maintained. 5. Amend the Regulation which establishes the right to appeal, the procedure, the body that reviews the appeal and the deadline for	

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
ry Kosov o Cham ber of Nurses (OIK)	No. OIK2-A	permission Licensing with college	-	authority Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<ol> <li>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.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure in the case of licensing is missing.</li> <li>The method of payment is more convenient but still restricted.</li> </ol>	<ul> <li>filing a complaint and deciding on the complaint.</li> <li>6. These changes can be made by amending the relevant Regulation.</li> <li>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> <li>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.</li> <li>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-</li> </ul>	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 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. Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing. Amendment of Decision on Administrative Fees
						<ul><li>banking, POS, etc. Accept any proof of payment.</li><li>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li></ul>	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. The fee and any other payment should be in

Minist ry	Ref. No.	Name of permission	Type of permis sion	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.
Kosov o Cham ber 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> <li>The OIK2-B license should be issued for an indefinite term.</li> <li>The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</li> <li>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.</li> <li>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,</li> </ol>	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).

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>and the examination process can be continued to prove that the professional qualifications have been maintained.</li> <li>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.</li> <li>6. These changes can be made by amending the Perulation</li> </ul>	
Kosov O Cham ber 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	<ol> <li>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.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure in the case of licensing is missing.</li> <li>The method of payment is more convenient but still restricted.</li> </ol>	<ul> <li>the Regulation.</li> <li>1. Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> <li>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.</li> <li>4. Amend Decision on Administrative Fees for OIK Services so that payment is made at</li> </ul>	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 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 Further, the amendment of the regulation should be made to regulate the right to and procedure of appeal which is completely missing. Amendment of Decision on Administrative Fees for OIK Services should be done to enable

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>the end of the procedure and is also made through e-banking, POS, etc. Accept any proof of payment.</li> <li>5. The license should be signed by the Chair of the Chamber or by a Chamber official authorized for this purpose.</li> <li>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</li> </ul>	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. 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.
						recommended to calculate the costs incurred to provide this service (the World Bank can provide assistance for this).	
Kosov o Cham ber 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	<ol> <li>The OIK3-A license should be issued for an indefinite term.</li> <li>The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</li> <li>The only documents that can be requested are those that prove the achievement of 100 points, all other documents do not need to</li> </ol>	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).

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>be required because they exist and were provided during the first licensing process.</li> <li>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.</li> <li>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.</li> <li>6. These changes can be made by amending the Regulation.</li> </ul>	
Kosov o Cham ber of Nurses (OIK)	OIK4-A	Licensing of clinical psychologi sts	Licence	Licensing Commission; License is signed by the Chair of the Commission and the Chair of the Chamber	<ol> <li>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.</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The appeal procedure in the case of licensing is missing.</li> </ol>	<ol> <li>Amend Law No. 04/L-150 on Chambers of Healthcare Professionals, listing in an annex all professional licenses issued by the chambers.</li> <li>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.</li> </ol>	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 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Cham ber of Nurses (OIK)		psychologi sts		License is signed by the Chair of the Licensing Commission and the Chair of the Chamber		<ol> <li>2. The 5-year term can be maintained but only for the purpose of valorization of 100 credit points for holding a basic license.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>6. These changes can be made by amending the Regulation No. 12/2019.</li> </ol>	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).
Kosov O Cham ber 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

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
		of war	sion				
		veterans,					
		veterans,					
		martyrs,					
		war					
		invalids,					
		civilian					
		victims and					
		their					
		families					
Kosov	OIK6	License	License	Licensing	This should not be included in	1. Require only a request with minimum data	There is no need and no argument for
0		duplicate		Commission;	the register as it is not a new	to make known the fact of loss or damage of	implementing a procedure and convening the
Cham		(license		Liegenee is signed	license	the license.	Licensing Commission to decide on an action as
ber of Nurses		сору)		License is signed by the Chair of the		2. Other data are or should be in the register	simple as the issuance of a duplicate copy, which can easily be ascertained and issued by
(OIK)				Commission and		of licenses kept by the chamber.	the professional service of the Chamber.
				the Chair of the		of incenses kept by the chamber.	the professional service of the chamber.
				Chamber		3. The duplicate copy should be signed by	
						the Chair of the Chamber or by a Chamber	
						official authorized for this purpose.	
Divisio	DLAIS	License for	Permit	Board for	1. Law No. 04/L-125 on Health in	1. Amend Law No. 04/L-125 on Health, listing	Amendment of Law No. 04/L-125 on Health is
n for	H1	general		Licensing of	Article 42 provides only for the	in an annex all permits for which the	needed to harmonize this Law with Article 17,
Licensi		hospital		Private Healthcare	obligation to be licensed to	Ministry of Health is competent.	paragraph, 1 of Law No. 04/L-202 on Permit and
ng and				Institutions;	commence work but does not		License System, according to which a permit and
Accred					stipulate this type of license	2. Amend Administrative Instruction No.	license can be defined only by law.
itation				License is signed	specifically;	08/2014 on Procedures for licensing of	Amendment of Administrative Instruction No.
of				by the Minister and the Chair of	2 Sublegel acts that regulate	private healthcare institutions, to require	08/2014 Procedures for licensing of private
Health care				the Board	2. Sub-legal acts that regulate this license, in addition to not	only information, to be submitted ex officio, without needing to submit documents such	healthcare institutions should be done to harmonize with Article 16 of Law No. 04/L-202
Institu					having a clear legal basis, do not	as: Identification documentation for the	on Permit and License System, but also to
tions					regulate it specifically;	founder, director and health personnel,	ensure compliance with the principle of
					i eguiace it specifically,	Certificate of business registration,	conducting ex officio procedures under the
					3. The license is issued for a	professional licenses for health personnel;	LGAP. The change from a registered document

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					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;	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;	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.
					<ul><li>4. Some of the documents do not need to be requested from the party.</li><li>5. The right to appeal is regulated by a sub logal act and</li></ul>	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	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.
					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.	<ul> <li>complaint and deciding on the complaint in accordance with LGAP.</li> <li>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</li> </ul>	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.
					<ul><li>6. The method of payment is inappropriate, and payment is not refunded if the license is denied.</li><li>7. The register of licenses is</li></ul>	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.	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.
					<ul><li>8. Decision making through a</li></ul>	6. Create/complete the license register with all the elements contained by the license.	Delegation of decision-making to the unit/responsible official is an obligation under
					<ol> <li>Decision making through a licensing board is unnecessary.</li> <li>The designation is incorrect as</li> </ol>	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 because the substantive competence for this permit has been given to the MoH and therefore there is no need to create such
					a license is issued to a natural		boards;

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					person for engaging in a profession that poses a medium or high risk to public health. 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; 11. There are no rules concerning suspension, revocation and transfer of this permit;	<ul> <li>8. Transfer the decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</li> <li>9. Change the category of permit from license to permit.</li> <li>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.</li> <li>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.</li> <li>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).</li> </ul>	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,

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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
	NO.	permission	-	authority	<ul> <li>absent.</li> <li>6. The method of payment is inappropriate, and payment is not refunded if the license is denied.</li> <li>7. The register of licenses is missing or incomplete.</li> <li>8. Decision making through a licensing board is unnecessary.</li> <li>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.</li> <li>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.</li> <li>11. There are no rules concerning suspension, revocation and transfer of this permit.</li> </ul>	<ul> <li>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.</li> <li>6. Create/complete the license register with all the elements contained in the license.</li> <li>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.</li> <li>8. Transfer decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</li> <li>9. Change the category of permit from license to permit.</li> <li>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.</li> </ul>	of and loss of time for payment as well as to abolish the restriction of only one form of payment proof accepted. 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 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. 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.
						11. The rules of Law No. 04/L-202 on Permit and License System apply vis-a-vis	

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						suspension, revocation and transfer of this permit. 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).	
Divisio n for Licensi ng and Accred itation of Health care	DLAIS H3	License for single activity ambulance (specialist ambulance )	Permit	Board for Licensing of Private Healthcare Institutions; License is signed by the Minister and the Chair of the Board	<ol> <li>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.</li> <li>Sub-legal acts that regulate this license, in addition to not</li> </ol>	<ul> <li>13. The fee for adding new hospital activity is also very high and needs to be reconsidered.</li> <li>1. Amend Law No. 04/L-125 on Health, listing in an annex all permits for which the Ministry of Health is competent.</li> <li>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</li> </ul>	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
Institu tions					<ul><li>having a clear legal basis, do not regulate it specifically.</li><li>3. The license is issued for a</li></ul>	as: Identification documentation for the founder, director and health personnel, Certificate of business registration, professional licenses for health personnel	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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					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.	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;	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.
					<ul> <li>4. Some of the documents do not need to be requested from the party.</li> <li>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 file the deadline for file the deadline for the deadli</li></ul>	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.	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. Amendment of Administrative Instruction No. 08/2014 on Procedures for licensing of private
					<ul><li>deadline for decision-making on the complaint is completely absent.</li><li>6. The method of payment is</li></ul>	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.	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.
					inappropriate, and payment is not refunded if the license is denied. 7. The register of licenses is	Accept any proof of payment. In case the issuance of this permit is refused, all payments made by the party will be returned.	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
					missing or incomplete.	6. Create/complete the license register with all the elements contained in the license.	bodies.
					8. Decision making through a licensing board is unnecessary.	7. The permit should be signed by the head of the unit, respectively the responsible	Delegation of decision-making to the unit/responsible official is an obligation under the LGAP because the substantive competence
					9. The designation is incorrect as a license is issued to a natural	official in the MoH appointed in accordance with the LGAP.	for this permit has been given to the MoH and therefore there is no need to create such
Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
--------------	-------------	--------------------	---------------------------	--------------------------	--	---	--
					<ul> <li>person for engaging in a profession that poses a medium or high risk to public health.</li> <li>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.</li> <li>11. There are no rules concerning suspension, revocation and transfer of this permit.</li> </ul>	<ul> <li>8. Transfer decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</li> <li>9. Change the category of permit from license to permit.</li> <li>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.</li> <li>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.</li> <li>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).</li> </ul>	boards; 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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Divisio n for Licensi ng and Accred itation of Health care Institu tions	DLAIS H4	License for ambulance s with two activities	Permit	Board for Licensing of Private Healthcare Institutions; License is signed by the Minister and the Chair of the Board	<ol> <li>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;</li> <li>Sub-legal acts that regulate this license, in addition to not having a clear legal basis, do not regulate it specifically;</li> <li>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;</li> <li>Some of the documents do not need to be requested from the party.</li> <li>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.</li> </ol>	<ol> <li>Amend Law No. 04/L-125 on Health and in an annex to list all permits for which the Ministry of Health is competent.</li> <li>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.</li> <li>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.</li> <li>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 the deadline for filing a complaint and deciding on the complaint in accordance with LGAP.</li> <li>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</li> </ol>	<ul> <li>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.</li> <li>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.</li> <li>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.</li> <li>Amendment of Administrative Instruction No. 08/2014 on Procedures for Licensing of Private Healthcare Institutions should be made 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.</li> </ul>

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
-			sion				
			permis	-	<ul> <li>6. The method of payment is inappropriate, and no payment will be refunded if the license is denied.</li> <li>7. The register of licenses is missing or incomplete.</li> <li>8. The way of decision making through a licensing board is unnecessary.</li> <li>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.</li> <li>10. The evaluation of the fulfillment of the conditions of the space, the personnel and</li> </ul>	<ul> <li>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.</li> <li>6. Create/complete the license register with all the elements contained in the license.</li> <li>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.</li> <li>8. Transfer decision-making responsibility from the board to a unit/responsible official within the MoH as defined by the LGAP.</li> <li>9. Change the category of permit from license to permit.</li> </ul>	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/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; 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
					the medical equipment is done through an evaluation commission appointed by the minister; 11. There are no rules concerning suspension, revocation and transfer of this permit;	<ul> <li>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.</li> <li>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.</li> </ul>	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	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).	
Divisio	DLAIS	Ambulance	Permit	Licensing Board of	1. Law no. 04 / L-125 on Health	1. To amend law no. 04 / L-125 on Health	Amendment of law no. 04 / L-125 on Health has
n for	H3	license		Private Health	in article 42 foresees only the	and in an annex to list all licences for which	to harmonize this law with article 17, paragraph
Licensi		with one		Care Institutions;	obligation to be licensed to start	the Ministry of Health is competent.	1 of Law no. 04 / L-202 on the system of permits
ng and		activity			work but nowhere doesnt	2. To change the Administrative Instruction	and licenses according to which a permit and
Accred		(specialist		The license is	foresee for this type of license	No. 08/2014 Procedures for licensing of	license can be defined only by law.
itation		ambulance		signed by: the	specifically;	private health institutions, where only	Amendment of Administrative Instruction No.
of		)		Minister and the		informations are required and the same	08/2014 Procedures for licensing of private
Health				Chairman of the	2. Bylaws that regulate this	have to be provided ex officio and not	health institutions should be done to harmonize
Institu				Board	license, except that they do not	documents such as: Identification	with Article 16 of Law no. 04 / L-202 on the
tions					have a clear legal basis, also	documentation for the founder, director and	system of permits and licenses but also on the
					nowhere specifically regulate	health personnel, Certificate of business	principle of conducting the procedure ex officio
					the same	registration, professional licenses for health	according to the LPPA. The change from a
						personnel;	registered document to a request, such as
					3. The license is issued for a	3. To amend the Administrative Instruction	requesting personal data instead of a copy of
					period of 5 years which is	No. 08/2014 on the procedures for licensing	the identity card, is done in order to enable
					determined by by the law and	private health institutions and to grant this	electronic communication, including the
					after the expiration of this term	licence without deadline by deleting the	interconnection of electronic systems.
					the relicensing must be done for	validity period and the need for relicensing;	Further, the amendment of the Administrative
					which the same procedure as	4.To amend the Administrative Instruction	Instruction No. 08/2014 on Procedures for

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					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 LGAPwhile the deadline for decision-making on the complaint is lacking completely 6. The method of payment is inconvenient and non- returnable. 7. The register of licenses is lacking or incomplete. 8. Manner of decision making through a licensing board is unnecessary. 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. 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; 11. There are no rules for suspension, revocation and	<ul> <li>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.</li> <li>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 ebanking, 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.</li> <li>6. To create / complete the license register with all the elements that the licence contains</li> <li>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;</li> <li>8. To change the way of decision making by the board in a unit / responsible official within the MOH as defined by the LPPA;</li> <li>9. To change the category of licence from license to licence;</li> <li>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</li> </ul>	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 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. Delegation of decision-making to the unit / 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; 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.

Minist Ref. Nam ry No. permis		Responsible authority	Findings	Recommendations	Rationale
DivisioDLAISLicensn forH4ambulaDivisiowith tvn foractivitiLicensiandAccredactivitiitationofHealthcareInstituitons	ance vo	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	transfer of this licence; 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; 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	commission; 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. 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). 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. 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; 3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this	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. 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, fo rexample requesting personal data instead of a copy of the identity card, in order to enable

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
			sion		relicensing must be done for 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 LGAPwhile the deadline for decision-making on the complaint is completely lacking. 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 through a licensing board is unnecessary. 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. 10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation	licence 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 LPPA. 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. 6. To create / complete the license register with all the elements that the license contains. 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; 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; 9. To change the category of permit from license to permit;	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 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. 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 / 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; 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
Ĺ					commission appointed by the	10. The evaluation of the fulfillment of the	made however does not guarantee that these

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					minister; 11. There are no rules for suspension, revocation and transfer of this licence;	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; 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. 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	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.
Divisio n for Licensi ng and Accred itation of Health care Institu tions	DLAIS H5	License for Polyclinic	Permit	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<ol> <li>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;</li> <li>Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</li> </ol>	<ul> <li>World Bank can provide assistance with this).</li> <li>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.</li> <li>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,</li> </ul>	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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
			sion		<ol> <li>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;</li> <li>Some of the documents do not need to be requested from the parties</li> <li>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 absent.</li> <li>The method of payment is inappropriate and payment will not be returned if the license is denied.</li> <li>The register of licenses is missing or incomplete.</li> <li>The way of decision making through a licensing board is unnecessary.</li> <li>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.</li> </ol>	professional licenses for health personnel; 3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence wihout 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 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. 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 with all the elements that the licence contains 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; 8. To change the way of decision making from the board to one unit /or the	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. 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. 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 information with other public bodies. 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; Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an
1					fulfillment of the conditions of		assessment by an evaluation commission for

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					the space, the personnel and the medical equipment is done through an evaluation commission appointed by the minister; 11. The rules for suspension, revocation and transfer of this licence are missing;	<ul> <li>defined by the LPPA;</li> <li>9. To change the category of licence from license to permit;</li> <li>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;</li> <li>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.</li> <li>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).</li> <li>13. The fee for adding new activity in the polyclinic is also high and should be reconsidered.</li> </ul>	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.
Divisio n for Licensi ng and	DLAIS H6	License for family medicine center	Permit	Licensing Board of Private Health Care Institutions;	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	<ol> <li>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.</li> <li>To change the Administrative Instruction</li> </ol>	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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Accred				The license is	this type of license specifically;	No. 08/2014 Procedures for licensing private	license can be defined only by law.
itation				signed by: the	2. Bylaws that regulate this	health institutions, where only informations	Amendment of Administrative Instruction No.
of				Minister and the	license, except that they do not	are required and the same are to be	08/2014 Procedures for licensing of private
Health				Chairman of the	have a clear legal basis, also	provided ex officio and not documents such	health institutions should be harmonized with
care				Board	nowhere specifically regulate	as: Identification documentation for the	Article 16 of Law no. 04 / L-202 on the system of
Institu					the same;	founder, director and health personnel,	permits and licenses but also on the principle of
tions					3. The license is issued for a	Certificate of business registration,	conducting the procedure ex officio according to
					period of 5 years which is	professional licenses for health personnel;	the LPPA. The change from a registered (named)
					determined by bylaw and after	3. To amend the Administrative Instruction	document to a request, such as requesting
					the expiration of this term the	No. 08/2014 on the procedures for licensing	personal data instead of a copy of the identity
					relicensing must be done with	private health institutions and to grant this	card, is done in order to enable electronic
					the same procedure as for	licence wihout deadline by deleting the	communication, including the interconnection
					licensing;	validity period and the need for relicensing;	of electronic systems.
					4. Some of the documents do	4. To amend the Administrative Instruction	Further, the amendment of the Administrative
					not need to be requested from	No. 08/2014 Procedures for licensing of	Instruction No. 08/2014 on Procedures for
					the parties	private health institutions in which are	licensing of private health institutions should be
					5. The right to appeal is	established the rules for the admissibility of	made to regulate the right and procedure of the
					regulated by a bylaw and the	the complaint, the procedure, the body that	complaint which is completely lacking.
					deadline for filing a complaint is	reviews the complaint and the deadline for	Amendment of Administrative Instruction No.
					shorter than defined by the	filing a complaint and deciding on the	08/2014 on Procedures for licensing of private
					LGAP while the deadline for	complaint in accordance with LPPA.	health institutions should be made to enable
					decision-making on the	5. To amend the Administrative Instruction	payment in the end to avoid frequency and loss
					complaint is completely lacking.	No. 08/2014 Procedures for licensing private	of time for payment and on the other hand not
					6. The method of payment is	health institutions in order for payments to	to limit only one form of evidence to prove
					inappropriate and payments will	be made at the end of the procedure and to	payment.
					not be returned if the license is	be made through e-banking, POS, etc. Accept	The register of licenses is necessary especially in
					denied.	any proof proving payment. In case the	case of loss or damage of a license to duplicate
					7. The register of licenses is	issuance of this licence is refused, all	the same, but also to enable communication
					missing or incomplete.	payments made by the party shall be	and exchange of information with other public
					8. Manner of decision making	returned.	bodies.
					through a licensing board is	6. To create / complete the license register	Delegation of decision-making to the unit /
					unnecessary.	with all the elements that the licence	responsible officer is an obligation under the
					9. The designation is incorrect as	contains	LGAPbecause the substantive competence for

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health. 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; 11. There are no rules for suspension, revocation and transfer of this licence;	<ul> <li>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;</li> <li>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;</li> <li>9. To change the category of permit from license to permit;</li> <li>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;</li> </ul>	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 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.
Divisio n for Licensi ng and Accred itation of Health care Institu tions	DLAIS H7	Licence for Laboratory	Permit	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<ol> <li>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;</li> <li>Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</li> <li>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</li> </ol>	<ol> <li>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.</li> <li>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;</li> <li>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</li> </ol>	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. 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

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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					11. There are no rules for suspension, revocation and transfer of this licence;	the completion of an affidavit without the need to make visits by the evaluation commission; 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. 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).	therefore this control should be done through regular and occasional inspections and not at the beginning of the procedure.
Divisio n for Licensi ng and Accred itation of Health care Institu tions	DLAIS H8	License for radiology cabinet	Permit	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<ol> <li>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;</li> <li>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;</li> <li>The license is issued for a period of 5 years which is</li> </ol>	<ol> <li>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.</li> <li>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;</li> <li>To amend the Administrative Instruction</li> </ol>	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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
			SION		determined by bylaw and after the expiration of this term the relicensing must be done following same procedure as for licensing; 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 LGAPwhile 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. Manner of decision making through a licensing board is unnecessary. 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. 10. The evaluation of the fulfillment of the conditions of the space, the personnel and	<ul> <li>No. 08/2014 on the procedures for licensing private health institutions and to grant this licence to the wihout deadline by deleting the validity period and the need for relicensing;</li> <li>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 deciding on the complaint in accordance with LPPA.</li> <li>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.</li> <li>6. To create / complete the license register with all the elements that the licence contains.</li> <li>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;</li> <li>8. To change the way of decision making from the board to one unit / responsible official within the MoH as defined by the</li> </ul>	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. 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 payen. 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 / responsible official 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; 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
					the medical equipment is done	LPPA;	made however does not guarantee that these

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
			sion		through an evaluation commission appointed by the minister; 11. There are no rules for suspension, revocation and transfer of this licence; 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.	<ul> <li>9. To change the category of licence from permit to licence;</li> <li>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;</li> <li>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.</li> <li>12. To repeal the Administrative Instruction No. 03/2007 Application of ionizing and nonionizing rays in health and to approve the new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health.</li> <li>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).</li> </ul>	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. 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.
Divisio n 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,

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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					through a licensing board is unnecessary. 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. 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; 11. There are no rules for suspension, revocation and transfer of this licence; 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.	contains	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; 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. 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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Divisio n for Licensi ng and Accred itation of Health care Institu tions	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	<ol> <li>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;</li> <li>Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</li> <li>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;</li> <li>Some of the documents do not need to be requested from the parties</li> <li>The right to appeal is regulated by a bylaw and the</li> </ol>	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). 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. 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. 3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence to the wihout 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	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. 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. Amendment of Administrative Instruction No.
					deadline for filing a complaint is shorter than defined by the LGAPwhile the deadline for	reviews the complaint and the deadline for filing a complaint and deciding on the complaint in accordance with LPPA.	08/2014 on Procedures for licensing of private health institutions should be made to enable payment in the end to avoid frequency and loss

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
			sion		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 through a licensing board is unnecessary. 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. 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; 11. There are no rules for suspension, revocation and transfer of this licence; 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.	<ul> <li>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.</li> <li>6. To create / complete the license register with all the elements that the licence contains</li> <li>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.</li> <li>8. To change the way of decision-making by the board in a unit / responsible official within the MoH as defined by the LPPA.</li> <li>9. To change the category of permission from license to licence.</li> <li>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.</li> <li>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.</li> <li>12. To repeal the Administrative Instruction No. 03/2007 Application of ionizing and nonionizing rays in health and to approve the</li> </ul>	of time for payment and on the other hand not to limit only one form of evidence to prove payen. 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 / 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; 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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						new Administrative Instruction that regulates this permission based on law no. 04 / L-125 on Health. 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).	
Divisio n for Licensi ng and Accred itation of Health care Institu tions	DLAIS H11	Cabinet license for computed tomograph -y	Permit	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<ol> <li>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;</li> <li>Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</li> <li>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</li> </ol>	<ol> <li>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.</li> <li>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.</li> <li>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</li> </ol>	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. 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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
			sion		a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health. 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	from license to permit. 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; 11. The rules for suspension, revocation and transfer of this licence to apply those defined in Law no. 04 / L-202 on the system	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. 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. 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 / 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; Giving an affidavit by a party to meet the requirements for space, staff and medical equipment is more reasonable than an
					minister; 11. There are no rules for	of licences and licenses. 12. To repeal the Administrative Instruction	assessment by an evaluation commission for several reasons, the first not to delay the

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					suspension, revocation and transfer of this licence; 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.	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. 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).	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. 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.
Divisio n for Licensi ng and Accred itation of Health care Institu tions	DLAIS H12	License for magnetic resonance cabinet	Permit	Licensing Board of Private Health Care Institutions; The license is signed by: the Minister and the Chairman of the Board	<ol> <li>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;</li> <li>Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</li> <li>The license is issued for a period of 5 years which is determined by bylaw and after the expiration of this term the</li> </ol>	<ol> <li>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.</li> <li>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.</li> <li>To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this</li> </ol>	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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
			sion		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 through a licensing board is unnecessary. 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. 10. The evaluation of the fulfillment of the conditions of the space, the personnel and the medical equipment is done through an evaluation	licence to the wihout 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 LPPA. 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 with all the elements that the licence contains 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. 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. To change the category of permission from license to licence.	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. 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 payen. 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 / 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; 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
					commission appointed by the	10. The evaluation of the fulfillment of the	made however does not guarantee that these

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
' y	140.	permission	sion	autionty			
					minister;	conditions for the space, the personnel and	conditions can be met from the first days,
					11. There are no rules for	the medical equipment to be done through	therefore this control should be done through
					suspension, revocation and	the completion of an affidavit without the	regular and occasional inspections and not at
					transfer of this licence;	need to make visits by the evaluation	the beginning of the procedure.
					12. Administrative Instruction	commission;	
					No. 03/2007 The application of	11. The rules for suspension, revocation and	Administrative Instruction No. 03/2007
					ionizing and non-ionizing rays in	transfer of this licence to apply those	Application of ionizing and non-ionizing rays in
					health is based on the Law on	defined in Law no. 04 / L-202 on the system	health really without legal basis, therefore the
					Private Health Activities which	of licences and licenses.	same should be repealed, a new administrative
					has been repealed by Law no. 04	12. To repeal the Administrative Instruction	instruction is drafted.
					/ L-125 on Health.	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	
						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).	
Divisio	DLAIS	License for	Permit	Licensing Board	1. Law no. 04 / L-125 on Health	1. To amend law no. 04 / L-125 on Health	Amendment of law no. 04 / L-125 on Health is
n for	H13	coronarogr		of Private Health	in article 42 provides only the	and in an annex to list all licences for which	needed to harmonized with article 17,
Licensi		aphy and		Care Institutions;	obligation to be licensed to start	the Ministry of Health is competent.	paragraph 1 of Law no. 04 / L-202 on the system
ng and		angiograph			work but nowhere does it	2. To change the Administrative Instruction	of licences and licenses according to which a
Accred		y cabinet		The license is	provide for this type of license	No. 08/2014 Procedures for licensing of	licence and license can be defined only by law.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
itation of Health care Institu tions				signed by: the Minister and the Chairman of the Board	<ul> <li>specifically;</li> <li>2. Bylaws that regulate this license, except that they do not have a clear legal basis, also nowhere specifically regulate the same;</li> <li>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;</li> <li>4. Some of the documents do not need to be requested from the parties</li> <li>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 absent.</li> <li>6. The method of payment is inappropriate and payment will not be returned if the license is denied.</li> <li>7. The register of licenses is missing or incomplete.</li> <li>8. The way of decision making through a licensing board is unnecessary.</li> <li>9. The designation is incorrect as</li> </ul>	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. 3. To amend the Administrative Instruction No. 08/2014 on the procedures for licensing private health institutions and to grant this licence to the wihout 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 LPPA. 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 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 with all the elements that the licence contains	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. 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 / responsible official is an obligation under the LGAPbecause the substantive competence for this licence has been given to the MoH and

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					a license which refers to a natural person for engaging in a profession that poses a medium or high risk to public health. 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; 11. There are no rules for suspension, revocation and transfer of this licence; 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.	<ol> <li>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.</li> <li>8. To change the way of decision-making by the board in a unit / responsible official within the MoH as defined by the LPPA.</li> <li>9. To change the category of permission from license to licence.</li> <li>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;</li> <li>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.</li> <li>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.</li> <li>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-202 on the system of licences and licenses (The fee that the competent authority may charge for a licence shall not exceed the amount</li> </ol>	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 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. 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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Depart ment of	DZHSS H1	Temporary work licence for	License	Licensing Board of Private Health Care Institutions;	1. Law no. 04 / L-125 on Health in article 71 paragraph 3 provides the obligation to be	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). 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	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 Strate gic Health Develo pment		licence for foreign doctors		Care Institutions; The license is signed by: the Minister and the Chairman of the Board	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;	<ul> <li>licences and licenses.</li> <li>2. To draft and approve the bylaw according to article 71 paragraph 3 of Law no. 04 / L-125 on Health</li> <li>3. This type of license to be granted indefinitely.</li> <li>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.</li> <li>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.</li> <li>6. The bylaw to enable the payment to be made at the end of the procedure and to be</li> </ul>	of licences and licenses according to which a licence and license can be defined only by law. 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. 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.
					<ul><li>4. Some of the documents do not need to be requested from the parties</li><li>5. There are no rules for the right to appeal;</li><li>6. The method of payment is</li></ul>	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	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. The restriction of the submission of the request

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					<ul> <li>inappropriate and payment will not be returned if the license is denied.</li> <li>7. The register of licenses is lacking or incomplete.</li> <li>8. The request is made by the legal person for the foreign citizen and not by the natural person requesting the licence</li> <li>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.</li> <li>10. There are no rules for the suspension and revocation of this license.</li> </ul>	<ul> <li>with all the elements that the licence contains</li> <li>8. The request to be allowed for the natural person in this case by the doctor with foreign citizenship;</li> <li>9. To change the category of licence from licence to professional permit.</li> <li>10. The rules for suspension, revocation of this licence to apply those defined in Law no.</li> <li>04 / L-202 on the system of licences and licenses.</li> </ul>	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.
Kosov o Medici nes Agenc y	AKPP M1	License for pharmaceu tical retailers (pharmacie s) of medicinal products and medical devices	Permit	Licensing Department of the KMA; Licence is signed by the Director and the CEO of KMA	<ol> <li>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;</li> <li>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;</li> </ol>	<ol> <li>Amend Law No 04/L-190 on Medicinal Products and Medical Devices to establish the conditions and criteria for this type of permission;</li> <li>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;</li> <li>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</li> </ol>	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. 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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					<ol> <li>Some of the documents do not need to be requested from the party.</li> <li>The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>The law envisages service fees for this type of permit, which is contrary to Article 12 of the LGAP.</li> <li>Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked;</li> <li>The license register is missing or incomplete.</li> <li>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.</li> <li>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;</li> <li>The rules for revocation and transfer of this permit are missing.</li> </ol>	business issued with code of activity for retail circulation of pharmaceutical products, Professional license of pharmacist, Work license of other professional staff; 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; 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; 6. Create/complete the register of licenses with all the elements contained in the license; 7. Change the way of decision-making for this license and delegate responsibility to the professional employee as provided for in	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. 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 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. 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 competencies is a legal requirement of the LGAP, including the signing of the license. Revocation rules are necessary, even if only as a reference to Law No. 04/L-202 on Permit and License System.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						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; 9. Change the category of permission from license to permit; 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; 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	
Kosov o Medici nes Agenc y	AKPP M2	License for pharmaceu tical wholesaler s (warehous es) of medicinal products and medical devices	Permit	Licensing Department of the KMA; Licence is signed by the Director and the CEO of KMA	<ol> <li>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;</li> <li>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;</li> <li>Some of the documents do not need to be requested from the party.</li> <li>The right to appeal is not fully</li> </ol>	revocation and transfer of this permit. 1. Amend Law No 04/L-190 on Medicinal Products and Medical Devices to establish the conditions and criteria for this type of permission; 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; 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;	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. 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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
			31011		regulated and is not in accordance with the LGAP. 5. The law envisages service fees for this type of permit, which is contrary to Article 12 of the LGAP. 6. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked; 7. The license register is missing or incomplete. 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. 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; 10. The rules for revocation and transfer of this permit are missing.	<ul> <li>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;</li> <li>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;</li> <li>6. Create/complete the register of licenses with all the elements contained in the license;</li> <li>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;</li> <li>9. Change the category of permission from license to permit;</li> <li>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;</li> </ul>	officio according to the LGAP. 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 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. 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 competencies is a legal requirement of the LGAP, including the signing of the license. Revocation rules are necessary, even if only as a reference to Law No. 04/L-202 on Permit and License System.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						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.	
Kosov o Medici nes Agenc y	AKPP M3	License for the import of medicinal products	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<ol> <li>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;</li> <li>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.</li> <li>There is no need for some of the documents to be requested from the party.</li> <li>The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</li> <li>In addition to service fees, a fee of 1% of the imported products' invoice value is envisaged;</li> <li>The Registry for Licenses is missing or is incomplete.</li> </ol>	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 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; 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;	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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					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. 9. The rules for revocation and transfer of this permit are missing.	<ul> <li>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.</li> <li>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.</li> <li>6. Remove the tariff at the amount of 1% of the imported products.</li> <li>7. Establish/complete the Registry for Licenses with all the elements that the license contains.</li> <li>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; 9. Change the permission category from license to permit; 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.</li> </ul>	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Kosov o Medici nes Agenc y	AKPP M5	License for the import of refurbishe d equipment	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<ol> <li>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;</li> <li>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.</li> <li>Some of the documents are not necessary to be requested from the party.</li> <li>The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</li> <li>In addition to service fees, a fee of 1% of the invoice value of imported products is envisaged;</li> <li>The register of licenses is missing or is incomplete.</li> <li>The designation as a license which refers to a natural person for engaging in a profession that poses a medium or high risk to</li> </ol>	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; 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; 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, and should meet the GMP standards; 4. Amend the Law 04/L-190 on Medicinal Products and Medical Devices, which establishes the rules for the admissibility of	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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					public health is improper. 9. The rules for revocation and transfer of this permit are missing.	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. 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. 6. Remove the tariff at the amount of 1% of the imported products. 7. Establish/complete the Registry for Licenses with all the elements that the license contains. 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; 9. Change the permission category from license to permit; 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.	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.
Kosov o 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
	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
-------------------	-------------	--	---------------------------	---	--	--	---
nes Agenc y		products (not registered in Kosovo)		The license is signed by: KMA Director and Chief Executive	permit in Article 12 but not with a specific name; 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. 3. Some of the documents are not necessary to be requested from the party. 4. The right to appeal is not fully regulated and is not in accordance with the LGAP. 5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP. 6. In addition to service fees, a fee of 1% of the invoice value of the imported products is envisaged; 7. The register of licenses is missing or is incomplete. 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. 9. The rules for revocation and	needed to obtain an import license, along with the conditions and criteria for obtaining those permits/licenses 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; 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; 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	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. 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

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
			sion				
					transfer of this permit are missing.	complaint in accordance with the LGAP. 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. 6. Remove the tariff at the amount of 1% of the imported products. 7. Establish/complete the Registry for Licenses with all the elements that the license contains. 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; 9. Change the permission category from license to permit; 10. Apply the rules on the revocation and transfer of this	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.
						permit as provided by Law No. 04/L-202 on	
Kosov	AKPP	License for	Permit	KMA Licensing	1. The license is issued for a	Permit and License System. 1. Amend Administrative Instruction No.	No reason has been provided as to why the
0	M7	import of		Department;	period of 3 months with the	06/2014 on determining the list of medicinal	license term is 3 + 3 months, therefore there is
Medici	1417	narcotic			possibility of extension for 3	products and borderline products which	no need for this type of license to be timely
		medicinal		The license is	additional months (maximum 6	require import and export authorizations	restricted.
nes					•		
Agenc		products		signed by: KMA	months). After the elapse of this	and this permit to be given for an indefinite	Amendment of Administrative Instruction No.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
У				Director and Chief Executive	period, a new application should be filed from the beginning in order to be equipped this license. 2. Some of the documents are not necessary to be requested from the party. 3. The right to appeal is not fully regulated and is not in accordance with the LGAP. 4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP. 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. 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. 8. The rules for revocation and transfer of this permit are missing.	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 importer and 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	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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded. 5. Remove the tariff at the amount of 1% of the imported products. 6. Establish/complete the Registry of Licenses with all the elements contained by the license. 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; 8. Change the 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.	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.
Kosov o Medici nes Agenc y	AKPP M8	License for import of radiophar maceutical s	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	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; 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.	<ol> <li>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</li> <li>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; 3. Amend the Law 04/L-190 on Medicinal Products and Medical</li> </ol>	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. The amendment of the Administrative Instruction No.13/2013 on Wholesalers for Medicinal Products and Medical Devices should

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					<ul> <li>3. Some of the documents are not necessary to be requested from the party.</li> <li>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</li> <li>6. In addition to service fees, a fee of 1% of the imported products invoice value is envisaged;</li> <li>7. The register of licenses is missing or is incomplete.</li> <li>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.</li> <li>9. The rules for revocation and transfer of this permit are missing.</li> </ul>	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; 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. 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.	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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						<ul> <li>6. Remove the tariff at the amount of 1% of the imported products.</li> <li>7. Establish/complete the Registry for Licenses with all the elements that the license contains.</li> <li>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; 9. Change the permission category from license to permit; 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.</li> </ul>	reference to Law No. 04/L-202 on Permit and License System.
Kosov o Medici nes Agenc y	AKPP M9	License for import of denatured alcohol	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<ol> <li>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;</li> <li>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.</li> <li>Some of the documents are not necessary to be requested from the party.</li> </ol>	<ol> <li>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;</li> <li>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; 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</li> </ol>	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. 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,

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					<ul> <li>4. The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>5. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</li> <li>6. In addition to service fees, a fee of 1% of the invoice for imported products is envisaged;</li> <li>7. The Registry of Licenses is missing or is incomplete.</li> <li>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.</li> <li>9. The rules for revocation and transfer of this permit are missing.</li> </ul>	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; 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. 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. 6. Remove the tariff at the amount of 1% of the imported products. 7. Establish/complete the Registry for	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Kosov o Medici nes Agenc y	AKPP M10	License for import of precursors	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<ol> <li>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.</li> <li>Some of the documents are not necessary to be requested from the party.</li> </ol>	Licenses with all the elements that the license contains. 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; 9. Change the permission category from license to permit; 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. 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; 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	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. 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
					3. The right to appeal is not fully regulated and is not in accordance with the LGAP. 4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP. 5. In addition to service fees, a	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	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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					fee of 1% of the imported products invoice value is envisaged; 6. The Registry of Licenses is missing or is incomplete. 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. 8. The rules for revocation and transfer of this permit are missing.	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 confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded. 5. Remove the tariff at the amount of 1% of the imported products. 6. Establish/complete the Registry of Licenses with all the elements contained by the license. 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; 8. Change the	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
	AKPP M11	License for import of psychotrop ics	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<ol> <li>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.</li> <li>Some of the documents are not necessary to be requested from the party.</li> <li>The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</li> <li>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.</li> <li>The designation as a license which refers to a natural person for engaging in a profession that</li> </ol>	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. 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; 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	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. 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. 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 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					public health is improper. 8. The rules for revocation and transfer of this permit are missing.	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 confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded. 5. Remove the tariff at the amount of 1% of the imported products. 6. Establish/complete the Registry of Licenses with all the elements contained by the license. 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; 8. Change the 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.	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.
Kosov	AKPP	License for	Permit	KMA Licensing	1. Law No. 04/L-190 on	1. Amend the Law 04/L-190 on Medicinal	The amendment of Law 04/L-190 on Medicinal
0	M12	import of		Department;	Medicinal Products and Medical	Products and Medical Devices, listing in an	Products and Medical Devices is needed in order
Medici		raw			Devices refers to this type of	annex all prerequisite permits or licences	to harmonize this law with Article 17, paragraph
nes		material -		The license is	permission in Article 12 but not	needed to obtain an import license, along	1 of Law No. 04/L-202 on Permit and License
Agenc		active		signed by: KMA	with a specific name;	with the conditions and criteria for obtaining	System, which stipulates that a permit and

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Y		substance		Director and Chief Executive	<ol> <li>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.</li> <li>There is no need for some of the documents to be requested from the party.</li> <li>The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP.</li> <li>The Registry of Licenses is missing or is incomplete.</li> <li>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.</li> <li>The rules for revocation and transfer of this permit are missing.</li> </ol>	those permits/licenses; 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; 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 importer and issued by the KMA or import license issued by the KMA, and should meet the GMP standards; 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. 5. Amend the Law 04/L-190 on Medicinal	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. 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 be made in order to argunat 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						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. 6. Establish/complete the Registry of Licenses with all the elements contained by the license. 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; 8. Change the 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.	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.
Kosov o Medici nes Agenc Y	AKPP M13	License for import of raw material - auxiliary substance	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	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; 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	<ol> <li>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;</li> <li>Amend Administrative Instruction No. 06/2014 on determining the list of medicinal products and borderline products which require import and export authorizations</li> </ol>	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

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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
Kosov	АКРР	License for	Permit	KMA Licensing	1. Law No. 04/L-190 on	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. 6. Establish/complete the Registry of Licenses with all the elements contained by the license. 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; 8. Change the 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. 1. Amend the Law 04/L-190 on Medicinal	reference to Law No. 04/L-202 on Permit and License System.
o Medici nes Agenc y	M14	the production of medicinal products		Department; The license is signed by: KMA Director and Chief Executive	Medicinal Products and Medical Devices refers to this type of permission in Article 10 as an authorization for production; 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; 3. The right to appeal is not fully regulated and is not in	<ul> <li>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;</li> <li>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.</li> <li>Amend the Law 04/L-190 on Medicinal products and Medical Devices and remove</li> </ul>	done. Therefore the need for re-licensing is unjustifiable and an unnecessary burden for the party. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					accordance with the LGAP. 4. The law envisages service fees for this type of permission, which is contrary to Article 12 of the LGAP. 5. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked; 6. Registry of Licenses is missing or is incomplete. 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. 8. The rules for revocation and transfer of this permit are missing.	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. 4. Establish/complete the Registry of Licenses with all the elements contained by the license. 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; 6. Change the permission category from license to permit; 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.	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.
Kosov O Medici nes Agenc Y	AKPP M15	License for galenic laboratory	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<ol> <li>Law No. 04/L-190 on Medicinal Products and Medical Devices mentions this type of permission in Article 10 as an authorization for production;</li> <li>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</li> </ol>	<ol> <li>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;</li> <li>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</li> </ol>	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. 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

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

Minist ry	Ref. No.	Name of permission	Type of permis	Responsible authority	Findings	Recommendations	Rationale
0	M16	operation	sion	Department;	period of 5 years, and after the	indefinite period of time in which case the	done. Therefore the need for re-licensing is
0 Medici	11110	with		Department,	expiration of this period the	validity period and the need for relicensing	unjustifiable and an unnecessary burden for the
nes		narcotics		The license is	relicensing must be done for	should be deleted;	party.
Agenc		narcotics		signed by: KMA	which the same procedure as	2. Amend the Administrative Instruction	The amendment of the Administrative
-				Director and Chief	for licensing must be followed;	(MoH) No.11/2015 - Retailers for Medicinal	Instruction (MoH) No.11/2015 on Retailers for
У				Executive	2. There is no need for some of	Products and Medical Devices, where only	Medicinal Products and Medical Devices should
				LACULIVE	the documents to be requested	the information would be required, and the	be made in order that it contains the
					from the party.	same should be provided ex officio, rather	information provided in paragraph 12 of the
					3. The right to appeal is not fully	than documents such as: Copy of work	Law No. 04/L-202 on Permit and License System,
					regulated and is not in	license (as wholesaler, retailer, or health	in order to harmonize it with Article 16 of Law
					accordance with the LGAP.	institution), Copy of the work license of the	No. 04/L-202 on Permit and License System but
					4. The law envisages service fees	responsible person, Copy of the identity card	also with the principle of conducting an ex
					for this type of permission,	of the director and the responsible person,	officio procedure based on the LGAP.
					which is contrary to Article 12 of	Certificate from the court regarding the	Amendment of Law 04/L-190 on Medicinal
					the LGAP.	criminal statute (for the director and the	Products and Medical Devices should be made
					5. Payment for this license can	responsible person, original or notarized, not	in order to regulate the right and appeals
					be made in installments for each	older than 6 months),	procedure which is missing. The amendment of
					year, while if the installment is	3. Amend the Law 04/L-190 on Medicinal	Law 04/L-190 on Medicinal Products and
					not paid, the license is revoked;	Products and Medical Devices, which	Medical Devices should remove all taxes for
					6. Registry of Licenses is missing	establishes the rules for the admissibility of	services while the license fees should be
					or is incomplete.	the complaint, the procedure, the body that	determined pursuant to Article 12 of the LGAP.
					7. The designation as a license	reviews the complaint and the deadline for	Additionally, it should envisage rules to enable
					which refers to a natural person	filing a complaint and deciding on the	the payment in the end, in order to avoid
					for engaging in a profession that	complaint in accordance with the LGAP.	frequency and time loss for payment, and on
					poses a medium or high risk to	4. Amend the Law 04/L-190 on Medicinal	the other hand not to envisage only one form of
					public health is improper.	products and Medical Devices and remove	proof in order to prove the payment.
					8. The evaluation of the	all taxes for services and impose tariffs in	The Registry of Licenses is necessary especially
					fulfillment of several criteria is	accordance with Article 12 of the LGAP. The	in case of loss or damage of a license in order to
					done in the field by the senior	payment should be made at the end of the	duplicate the same, but also to enable
					officials of the KMA. This is a	procedure and should also be done through	communication and exchange of information
					mandatory phase of the	e-banking, POS, etc. Accept any proof which	with other public bodies.
					procedure and is charged for;	confirms payment. In case the issuance of	The delegation of the decision-making
					9. The rules for revocation and	the permit is rejected, all payments made by	competence, including the signing of a license, is

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					transfer of this permit are missing.	<ul> <li>the party should be refunded.</li> <li>5. Establish/complete the Registry of Licenses with all the elements contained by the licenses.</li> <li>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.</li> <li>7. Change the permission category from license to permit.</li> <li>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.</li> <li>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.</li> </ul>	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.
Kosov o Medici nes Agenc y	AKPP M17	License for operation with precursors	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	<ol> <li>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;</li> <li>There is no need for some of the documents to be requested from the party.</li> <li>The right to appeal is not fully regulated and is not in accordance with the LGAP.</li> <li>The law envisages service fees</li> </ol>	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; 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	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. 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

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					for this type of permission, which is contrary to Article 12 of the LGAP. 5. Payment for this license can be made in installments for each year, while if the installment is not paid, the license is revoked; 6. Registry of Licenses is missing or is incomplete. 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. 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; 9. The rules for revocation and transfer of this permit are missing.	the identity card of the director and the responsible person. 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 confirms payment. In case the issuance of the permit is rejected, all payments made by the party should be refunded. 5. Establish/complete the Registry of Licenses with all the elements contained by the license. 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. 7. Change the permission category from license to permit. 8. The assessment of compliance with the conditions and criteria to be done by	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.

Minist ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
						completing an affidavit without senior KMA officials having the need to make a visit. 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.	
Kosov o Medici nes Agenc y	AKPP M18	License for import of medicinal products for individual therapy	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	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.
Kosov o Medici nes Agenc y	AKPP M19	License for export of medicinal products	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	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.
Kosov o Medici nes Agenc y	AKPP M20	License for the export of medical devices	Permit	KMA Licensing Department; The license is signed by: KMA Director and Chief Executive	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.

Minis ry	Ref. No.	Name of permission	Type of permis sion	Responsible authority	Findings	Recommendations	Rationale
					product.		