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ENTERPRISE DEVELOPMENT AND MARKET COMPETITIVENESS (EDMC)

**DEFINING LICENSING REQUIREMENTS, GOVERNMENT AUTHORIZATIONS AND
INSPECTIONS APPLICABLE TO THE ENTITIES OPERATING IN HOSPITALITY,
FOOD PROCESSING, PHARMACEUTICAL/BIOTECHNOLOGY AND HIGH-TECH
VALUE CHAINS**

September 28, 2012

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ENTERPRISE DEVELOPMENT AND MARKET COMPETITIVENESS PROJECT

DEFINING LICENSING REQUIREMENTS, GOVERNMENT AUTHORIZATIONS AND INSPECTIONS APPLICABLE TO THE ENTITIES OPERATING IN HOSPITALITY, FOOD PROCESSING, PHARMACEUTICAL/BIOTECHNOLOGY AND HIGH-TECH VALUE CHAINS

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Summary of recommendations

This report, initiated by the Enterprise Development and Market Competitiveness Project (EDMC), intends to provide a comprehensive review (mapping) of licensing and government authorization requirements, procedures and inspections applicable to enterprises operating in hospitality, food processing, pharmaceutical/biotechnology and high-tech value chains.

The Report lists all licensing and government authorization requirements, procedures and inspections required by the current legislation of the Republic of Armenia (RA).

Based on our research some burdensome procedures are identified that can be recommended for elimination.

The table below consolidates the recommendations from the Report.

ISSUE	RECOMMENDATION
<p>1. <u>LICENSING AND GOVERNMENT AUTHORIZATION REQUIREMENTS IN HOSPITALITY</u></p> <p>The number of documents required for issuing the classification to hospitality accommodation needs to be streamlined.</p>	<p>The list of the documents required to be submitted for classification purposes needs to be precise and streamlined in order to avoid requiring documents which were mandated by outdated legislation that has subsequently been replaced or repealed.</p> <p>The timetable, duration and the periodicity of the periodic assessments in hospitality accommodations needs to be more precisely determined.</p>
<p>2. <u>LICENSING AND GOVERNMENT AUTHORIZATION REQUIREMENTS IN FOOD PROCESSING</u></p> <p>The price for the services of obligatory certification of conformity is calculated on the basis of labour-intensiveness of the particular scheme chosen. The list and labour-intensiveness coefficients were defined in 2001.</p>	<p>Taking into account that some works could be automated due to technical progress during the years, we suggest a periodic revision of the coefficients for labour-intensiveness or, alternatively, to set out definite prices for each type of service provided.</p>
<p>3. <u>Licensing and government authorization requirements in pharmaceutical/biotechnology</u></p>	

A new Law on Pharmaceuticals should be adopted which will address issues pertaining to the whole cycle starting from production and through to the consumption of medicine.

Establish a surveillance system to withdraw from the market expired and dangerous medicines.

4. Licensing and government authorization requirements in high-tech

Export procedures related to dual use goods need to be streamlined to ensure that the expert examinations are less costly and less time consuming for the exporters in the HT sector.

5. INSPECTION

Currently, the audit selection process appears intuitive.

There is a lack of formal procedures in place on the manner of conducting inspections and approaching issues by auditors.

Need to set out clear procedures on inspections.

The risk-based identification system needs to be enhanced to serve as an effective tool for audits. Enhancing the system should also help provide guidance to auditors on specific high-risk areas that deserve closer attention during the audit.

The audit manuals and audit methodology should be developed. Currently, there is no manual or guidelines on inspections.

Background and Scope

An improved business environment much depends on there being modern and efficient licensing and control systems in place. In that regard, licensing and government authorization procedures need to be streamlined and unnecessary administrative and regulatory burdens associated with licensing and government authorization procedures need to be reduced to achieve the objective of an efficient, effective and sound regulatory framework that supports business development and the competitiveness of the relevant sector.

Scope of Work

This report introduces a comprehensive review (mapping) of licensing and government authorization requirements, procedures and inspections applicable to entities operating in hospitality, food processing, pharmaceutical/biotechnology and high-tech value chains.

A. Hospitality

Licensing and Government Authorization Requirements in the Sector

As of January 1, 2012 there are 30 classified accommodation establishments in the Republic of Armenia (<http://mineconomy.am/eng/16/text.html>).

Hotels, motels, hotel type accommodations, health centers, recreation and specialized camps or houses, guesthouses, tourism, youth and camp complexes, tourism houses are the objects of accommodation establishments¹ None of these types of accommodation require any special license though they may be the subject of classification on a voluntary basis.

The Ministry of Economy (MoE) is responsible for classification of accommodation establishments, ensuring compliance and imposing sanctions in cases of violations.²

Only those types of accommodation establishment that comply with urban-planning, sanitary and hygienic, fire safety and tourism minimal requirements defined by the legislation of Armenia are eligible for classification. These are rated and granted a stars-based classification for the higher graded types of establishment or a grade based on a numbers' system for the rest³.

Logistical support and the list of services of the classified accommodation should comply with the awarded classification order requirements⁴.

List of required documents

For classification of an accommodation establishment an individual (for B&Bs), an individual entrepreneur or legal entity (hereinafter referred to as "Applicant") applies to the MoE (either electronically at the following e-mail address: secretariat@mineconomy.am or by submitting a hard copy of the application), indicating the expected type of classification of the accommodation establishment.

The following should be enclosed to the application⁵:

- a) The Act of Substantial Completion of the Building entered into force no earlier than 10 years before the application⁶, Technical Passport⁷ or other legal act confirming that the building is ready for utilization;

1 RA law N HO-11-N "On Tourism and Tourism Activities", 17 December 2003 (Art. 8, p. 2)

2 RA law N HO-11-N "On Tourism and Tourism Activities", 17 December 2003 (Art. 7, p. 5,6,7)

3 RA law N HO-11-N "On Tourism and Tourism Activities", 17 December 2003 (Art. 10)

4 Decree N 946-N of the Government of the Republic of Armenia, 10 June 2004 (Art. II)

5 Decree N 946-N of the Government of the Republic of Armenia, 10 June 2004 (Art. II)

- b) The conclusion of the Ministry of Emergency Situations (MoES) of Armenia as to the compliance of the accommodation establishment with the fire safety requirements defined by law and other legislation on fire safety requirements issued no earlier than 10 days before the date of filing of the application;
- c) The conclusion of the Ministry of Health (MoH) of Armenia on the sanitary-epidemiological security of the establishment, issued no earlier than 10 days before the date of filing⁸.
- d) Copy of Certificate of ownership or right of use of the applicant's real estate as an accommodation establishment;
- d) Information about state registration or a registration number⁹.

The receipt (the original) of proof of the paid duty¹⁰ should be enclosed with the application and presented to the MoE. The rates of the state duty depend on the claimed type of classification of an accommodation establishment¹¹.

Rates of state duties for classification of accommodation establishments and the account numbers are provided below¹²:

Classification rating	Rate of state duty	Account
Up to three-star hotels/ motels for each star per year	in the amount of 150- fold of the basic fee ¹³	900005167524
For four-star hotels/motels for each star per year	in the amount of 200-fold of the basic fee	900005167532

6 RA law N HO-217 "On Urban Development", 5 May 1998 (Art. 25)

7 Order of the Minister of Urban Development on November 25, 1998, N 168

8 Ra law N HO-43 "On Protection of sanitary-epidemiological security of population", 12 December 1992 (Art. 12, 13)

9 Decree N 636-N of the Government of the Republic of Armenia, 28 April 2011 (Art.1)

10 RA law N HO-186 "On State Duties", 12 December 1997

11 Decree N 946-N of the Government of the Republic of Armenia, 10 June 2004, Appendixes for classification criteria of accommodation establishment

12 RA law N HO-186 "On State Duties", 12 December 1997

13 The basic fee is 1000 AMD.

For five-star hotels/ motels for each star per year	in the amount of 250-fold of the basic fee	900005167540
For hotel type accommodation and recreation or health centers for each star per year	in the amount of 200-fold of the basic fee	900005167557
<i>For specialized and rest house or camp, boarding (guest)house, tourism, youth and camp accommodation (complex)</i>		
For the first class per year	in the amount of 150-fold of the basic fee	900005167565
For the second class per year	in the amount of 100-fold of the basic fee	900005167565
For the third class per year	in the amount of 50-fold of the basic fee	900005167565
<i>For the B&B / Bed and Breakfast</i>		
For the first class per year	in the amount of 15-fold of the basic fee	900005167573
For the second class per year	in the amount of 10-fold of the basic fee	900005167573
For the third class per year	in the amount of 5-fold of the basic fee	900005167573

Classification of the tourist accommodation establishments

- 15 days are required for the MoE to make a decision whether to grant the classification or deny the application.
- Compliance of the accommodation establishment with the classification terms is assessed by the Assessment Committee under the MoE.
- In the case where there has been a positive report by the Assessment Committee, the MoE makes a decision on granting the corresponding classification type to the accommodation establishment and provides the applicant with the classification certificate¹⁴, as defined by the Decree. The Classification certificate can be provided in languages other than Armenian.
- The classification certificate is provided for a 5-year period.
- For the prolongation of classification certificate, an application should be submitted minimum 3 months before the date of expiry of the original.

14 Decree N 946-N of the Government of the Republic of Armenia, 10 June 2004, Appendix for the form of certificate

- The grounds of certificate termination are defined by the Decree¹⁵.

The validity of the classification of certificate is cancelled upon one of the following reasons:

- Expiry of the terms set by the certificate.
- A request of the accommodation services provider. A classification certificate is cancelled the following day after the receipt of such a request by the Applicant.

- The MoE will terminate the classification in the following cases:

- The provider of accommodation services fails to notify the classification authority about the elimination of non-compliances within 10 days after the notification on non-compliance is received;
- The assessment following the notification on elimination of non-compliance shows that the non-compliance has not been properly addressed;
- The requirements of the classification order are violated twice during the same year by the operator of the accommodation establishment;
- The operator of the accommodation establishment creates impediments during the periodic assessments.

The decision of the classification authority (MoE) can be appealed to the courts.

Paying taxes

The accommodation establishments providing tourist services, that comply with the requirements of the order of the Ministry of Economy¹⁶, are taxed on the general bases, in other cases the annual patent fee shall be paid.

In the case of tourist services provision by B&Bs the individual person is considered as a taxpayer of the annual patent fee.¹⁷

15 Decree N 946-N of the Government of the Republic of Armenia, 10 June 2004 (Art III, p.27)

16 Order of the Ministry of Economy N 268-N adopted on 23 March 2012.

17 RA Law N HO-209 N"On Patent Fees", 22 December 2010.

Periodic assessment¹⁸

- To ensure compliance with the classification terms the MoE periodically assesses the conformity of the accommodation establishment (hereinafter referred to as “periodic assessment”). The MoE exercises this function through the Licensing and Permits Agency, which is a detached subdivision of the MoE.
- The periodic assessment is conducted without prior notification to the person providing the tourism services.

The official participating in the periodic assessment:

- Is entitled to enter the parts of the accommodation premises, to the extent necessary for assessment of conformity of the accommodation establishment to the classification requirements, in the presence of the tourism services provider’s representative or employee, and may demand relevant documentation necessary for the periodic assessment.
- Must not interfere with the operations of the accommodation establishment.
- After the periodic assessment, 2 copies of a protocol are prepared, in which the date and place of the assessment, titles of the classification authority and the accommodation establishment, names of the official(s) participating in the periodic assessment, the dates/duration of the periodic assessment and the results are stated.
- The protocols are signed by the officials who undertook the periodic assessment, and the owner or representative of the accommodation establishment.

Where non-compliance with the defined requirements is revealed during the periodic assessment the relevant authorities (the MoE) notifies the person operating the hospitality accommodation and sets out the steps necessary for eliminating the non-compliance.

Conclusions

The frequency and duration of the assessment and the criteria for selection of accommodation establishments for assessment is not addressed in the Government Decree. For the purposes of certainty and predictability it should be recommended that the Decree specifically address these issues.

Recommendations

Define a timeframe, duration and the periodicity of the periodic assessments of tourist accommodation establishments.

18 Decree N 946-N of the Government of the Republic of Armenia, 10 June 2004 (Art. V)

B. Licensing and Government Authorization Requirements in the Herbs, Fruits and Vegetables Sector

Fruits, vegetables and herbs and, in particular, fruit and vegetable juices and drinks that contain fruit and vegetable juices and nectar in accordance with codes 2202 90, 2007 99, 2009, 2202 90 100 codes of HS-CODE are required under the technical regulation¹⁹ to have a mandatory certificate on conformity.

This mandatory certification of conformity of the product is realized through:

- a conformity declaration;
- certification

Mandatory certification of conformity through the certification process is only required in the following cases:

- the product contains risks;
- where certification is mandatory according to international agreements;
- in the case where the entrepreneur is unable to provide evidence of the product conformity sufficient for a conformity declaration.

Thus, the entrepreneur can apply to the certification authority for:

- Product certification;
- Approval and registration of a product conformity declaration;
- Recognition and re-execution of foreign certificates.

The period of validity of the declaration or certificate cannot exceed 3 years. The product is granted a mark of conformity on the basis of the declaration or certificate.

The process of product mandatory certification of conformity usually takes 2-4 days.

Fees are collected for the services of the certification authorities and testing laboratories during the mandatory certification of conformity. The prices²⁰ for the services depend on the labour-intensiveness of the particular scheme²¹ chosen for mandatory certification of conformity.

19 "Technical Regulation of Requirements for Juices and Juice-products" approved by the Decree N744 of the Government of the Republic of Armenia, 26 June 2009.

20 Order N91 of the Ministry of Finance and Economy "On the Procedure of Calculating Prices of Operations of Mandatory Certification of Conformity", 20 March 2001.

Certification authorities and testing laboratories are accredited by the MoE. The MoE and the Ministry of Agriculture (MoA) are responsible for surveillance over the conformity of goods and services to the requirements of technical regulations. This surveillance on conformity and on meeting food safety regulations is conducted according to the law “On organizing and conducting inspections in the Republic of Armenia”²², on the basis of checklists, that are open to the public and are published on the official website of the above-mentioned authority.

Conclusion and Recommendations

The price for the services of mandatory certification of conformity is calculated on the basis of the labor-intensiveness of the particular scheme chosen for obligatory certification of conformity.

Taking into account that some aspects of this work may have been or become automated due to technical progress during the years, we recommend to revise periodically the coefficients for labor-intensiveness or to set up specific prices for each type of service provided.

21 Decree N 1170-N of the Government of the Republic of Armenia “On Defining the Schemes of Mandatory Certification of Goods or Services and Identification Marks”, 12 August 2004

22 RA law N HO-60 «“On Organizing and Conducting Inspections in the Republic of Armenia” 17 May 2000

C. Licensing and Government Authorization Requirements in the Pharmaceutical /Biotechnology Sector

According to the Classifier of Types of Economic Activities in Armenia (CTEA, Group 2), this group includes²³

Code	Name of the type of economic activity	License
21	Manufacture of pharmaceutical products	Required
21.1	Manufacture of basic pharmaceutical products	-
21.10	Manufacture of basic pharmaceutical products	Required
21.10.0	Manufacture of basic pharmaceutical products	-
21.2	Manufacture of pharmaceutical preparations and substances	-
21.20	Manufacture of pharmaceutical preparations and substances	Required
21.20.1	Manufacture of pharmaceutical preparations and substances	Required
21.20.2	Manufacture of veterinary medicines	Required

As indicated by the table, a license is required for the production of pharmaceutical products. The types of activity subject to licensing and relations relating to licensing are regulated by the Law “On Licensing” of the Republic of Armenia²⁴, RA Law “On Medicines”, international treaties of the Republic of Armenia and other legislative acts.

The RA Law “On Licensing” defines types of activity subject to licensing, types of licenses (licenses issued through simplified and compound licensing procedures), procedures on licensing, terms and conditions of licensing, licensing bodies, licensing requisites, etc.

Article 43 of the Law of the Republic of Armenia on Licensing states the following:

23 Order of the Ministry of Economy N 372-N adopted on 03 June 2009

24 RA Law N HO-193 “On Licensing”, 27 June 2001

Health sector	Type of activity subject to licensing	Licensor	Type of license	Expertise requirement	Qualification requirements	Reporting requirement	Location requirement
1	Production of medicines	AB	C	E	-	R	L
2	Pharmaceutical activities	AB	C	-	Q	-	L

AB – Public Administration Body, authorized by the Government of the Republic of Armenia. In this particular case, the licensing body is the Ministry of Health;

C – License issued through compound procedure.

The circulation of medicines in Armenia, including their manufacture, preparation, measure, packaging, registration, quality control and other actions relating to the receipt or destruction of drugs, acquisition, maintenance, storage, distribution, release, sale, export, import, information and advertising of medicines, as well as the powers of government bodies of Armenia in the above-mentioned areas are regulated by the Law of the Republic of Armenia “On Medicines”²⁵:

According to the law on “Medicines”, licenses for pharmaceutical activities are issued and revoked by the Ministry of Health, which acts as the authorised body.

Licenses for implementing pharmaceutical activities in Armenia are issued for:

- manufacture of drugs;
- processing of herbs;
- pharmacy operation;
- drug import and export;
- trade of narcotic drugs.

As we can see from the above mentioned laws in case of the law on “Licensing” the scope of licensing also includes the manufacture of drugs, pharmacy operation, however under the law on “Medicine” the list is wider.

The procedure for licensing of manufacture of medicines and pharmacy operation and the forms of licenses for these activities are established by the decision of the Government of the Republic of Armenia²⁶.

25RA Law N HO-259 “On Medicines”, 27 October 1998

26 Decree N 867 of the Government of the Republic of Armenia, 29 June 2002

The decision defines the procedure of licensing and the license forms for the manufacture of medicines and pharmacy operation, as well as terms and requirements for licensing, the list of documentation to be submitted to competent bodies to obtain licenses, etc.

Licenses for the manufacture of medicines are issued through the compound procedure.

State duty is charged for the issuance of license, in accordance with the procedure and at the amount stipulated by the Law of the Republic of Armenia on State Duties²⁷.

For obtaining licenses, business entities may also apply using the electronic system at <https://www.e-gov.am/licenses>. The procedure for the submission of documentation required for obtaining a license by the electronic system is established by the Government of Armenia²⁸.

Based on the Government decision, the Ministry of Health develops the terms and requirements for licensing and qualification and performs monitoring over their implementation²⁹.

In Armenia, it is permitted to produce, import, store, distribute, sell and administer medicines registered in Armenia. The state registration of medicines is performed individually for producers (firms) and countries. If one and the same entity produces the same medicine in different countries, the registration is performed for each individual producing country³⁰. The state registration of medicines is done on the basis of scientifically approved criteria of quality, efficiency and safety of medicines and the results of experimental research. Appraisal of medicines for the purpose of registration is performed by “Agency of Medicines and Medical Technologies” CJSC.

#	Cases of State Registration	Fees for expert opinions, including VAT (in thousand drams)
1.	Reproduced (generic) drugs' first formulation, dosage	900
	<i>each subsequent formulation</i>	450
	<i>each subsequent dosage</i>	240
	<i>each new indications</i>	450
2.		1200
3.	First formulation, dosage of medicines containing new medicinal substances (new active substances)	2250
	<i>each subsequent formulation, dosage</i>	1200
4.	First formulation, dosage of homeopathic medicines	240

27 RA Law N HO-186 “On State Duties”, 27 December 1997

28 Decree N 1283-N of the Government of the Republic of Armenia, 24 September 2010

29 Decree N 1300-N of the Government of the Republic of Armenia, 15 August 2002

30 Decree N-347 of the Government of the Republic of Armenia, 25 April 2001

	<i>each subsequent formulation, dosage and new indications</i>	60
5.	Herb preparations, other preparations of natural origin and food additives containing biologically active substances	240
6.	Reformulation of state registration certificate in connection with changes in the name of the producing firm, the product, packaging and other changes with no impact on the product's safety, efficiency and quality	24

To ensure the circulation of safe and quality drugs in Armenia and prevent the threat to the health of population arising from the use of drugs having undergone improper storage or transportation or with expired use, the Ministry of Health has issued an order to establish requirements to the maintenance, storage and transportation of medicines, including their gross sale³¹.

Prior to the circulation of new medicines in Armenia it is necessary to conduct clinical researches according to the procedure established by the Government³²; the objective of the procedure is to obtain information on the safety and efficiency of the medicine, as well as possible side effects.

Permission to conduct clinical researches should be obtained from the Ministry of Health. The Order of the Minister³³ defines the procedure of conducting expert examination with the purpose of state registration of medicines, the table of minimum quantity of samples of medicines to be submitted with the application, the conclusion form of the examination of a medicine with the purpose of registration, the form and description of the state registration certificate, the list of changes of medicines registered in Armenia that do not require new registration, and the procedure of determining whether the medicine should be included in the group of prescription or non-prescription medicines.

The Government of Armenia has established the procedure of supervision over the import and export of medicines and medicinal substances, which is a licensed activity in Armenia. The purpose of the procedure is to monitor the import of efficient, safe and quality medicines and medicinal substances to preserve the health of population and protect consumers' rights. The procedure of supervision over the import and export of medicines and medicinal substances established by the Government of the Republic of Armenia will prevent the import of non-registered, expired, counterfeit or non-quality medicines and medicinal substances to the Republic of Armenia³⁴.

31Order of the Minister of Health of the republic of Armenia, on September 9,2010, N 17-N

32Decree N- 63, of the Government of Republic of Armenia, 24 January 2002

33 Order of the Minister of Health of the Republic of Armenia March 07, 2012, 123-N

34Decree N 581 of the Government of the Republic of Armenia, 20 September 2000

An Order of the Minister of Health establishes the list of discrepancies connected to packaging of medicines imported into Armenia with their registration samples which affect the safety, efficacy and quality of the medicines³⁵.

The list of documents necessary for certifying medicines and/or medicinal substances imported to or exported from Armenia is approved by another Order of the Minister of Health³⁶.

Relations pertaining to the circulation of drugs and psychotropic substances in Armenia are regulated by the Law of the Republic of Armenia on Narcotic Drugs and Psychotropic Substances³⁷:

Licenses are issued by a licensing body (the Ministry of Health) through compound procedures.

According to the Law of the Republic of Armenia on Advertising³⁸, permissions for the advertising of medications, medical equipment and methods of medical treatment are provided by the Ministry of Health (MoH)³⁹.

The advertiser of medications and methods of medical treatment can be represented only by a business entity having a corresponding license for the manufacture of medicines, sale of medicines, pharmacy operation or medical aid and services.

For obtaining permission the advertiser should submit to the MOH the following:

- An Application in the defined form, that includes the name of the applicant and the type of the legal person (the advertiser) or the name and the second name of the private entrepreneur, address (location) of the organization or address at residence of the private entrepreneur, the place of activity, telephone number, type of the advertisement for which permission is being requested, including the specific name of the medication, medical equipment or method of medical treatment, note on the media which will be used to disseminate the advertisement, the time of dissemination of the advertisement;
- In case of advertisement of medications or methods of medical treatment – the corresponding copies of the licenses for the manufacture of medicines, trade of medicines, pharmacy operation, medical aid and services;
- In the case of advertisement of a medicine – a copy of the certificate of registration of that medicine in the Republic of Armenia;

35Order of the Minister of Health on October 10, 2011, N 2006-A

36Order of the Minister of Health of the Republic of Armenia on October 10, 2002, N 662

37RA Law N HO-518-N “On Narcotic Drugs and Psychotropic Substances”, 10 February 2003

38RA Law N HO-55 “On Advertising”, 30 April 1996

39Decree N 1608-N of the Government of the republic of Armenia, 02 November 2006

- In the case of advertising of medications, medical equipment or methods of medical treatment by print media or outdoor advertisement – the drafted outline of the advertisement;
- In the case of the advertisement of medication, medical equipment or method of medical treatment by electronic media – detailed description of the content of the advertisement;
- A copy of the state registration certificate of the legal person or private entrepreneur (the advertiser);
- If the request for the advertisement permission has been submitted by an authorized representative – the power of attorney provided to that representative.

Permissions are provided within 20 days upon submission of the complete package of the documents to the Ministry. If within that period the request for the advertisement permission has not been rejected, such request shall be deemed satisfied.

To organize the manufacture of safe and high-quality medicines, the Government has approved the rules of Good manufacturing Practices⁴⁰, which pertain to all business entities involved in the manufacture of medicines for humans and animals in the Republic of Armenia.

These rules regulate relations with regard to the requirements as to the quality of manufacture of medicines, quality control, organization of manufacture of medicines, employees of the organization involved in the manufacture of medicines and medicine production units.

Considering the importance of the sphere for Armenia, the Government has also approved the schedule of enforcement of Good Manufacturing Practices of medicines and implementation of reforms in the sphere of medicines circulation.⁴¹

The above list of regulatory laws, government and ministerial decisions indicates that the sector is heavily regulated.

Recommendation

The GOA should more clearly provide pharmaceutical activities subject to licensing in Armenia.

40Decree N 1603-N of the Government of the Republic of Armenia, 25 November 2010

41Decree N 734-N of the Government of the Republic of Armenia, 26 May 2011

Licensing and government authorization requirements in High Tech Sector

According to the Classifier of Types of Economic Activities in Armenia (CTEA, Group 2), the main components of this sector include the following⁴²:

- IT activities (code 62),
- Information service activities (code 63):

Code	Name of the type of economic activity	License
62	Computer programming, consultancy and related services in IT industry	Not required
62.01	Computer programming, consultancy and related services in IT industry	Not required
	Computer programming activities	
62.01.0	Computer programming activities	Not required
62.02	Computer consultancy in IT industry	Not required
62.02.0	Computer consultancy in IT industry	Not required
62.03	Computer facilities management activities	Not required
62.03.0	Computer facilities management activities	Not required
62.09	Other information technology and computer service activities	Not required
62.09.0	Other information technology and computer service activities	Not required
63	Information service activities	Not required
63.1	Data processing, hosting and related activities; web portals	Not required
63.11	Data processing, hosting and related activities	Not required
63.11.0	Data processing, hosting and related activities	Not required
63.12	Web portals	Not required
63.12.0	Web portals	Not required
63.9	Other information service activities	Not required
63.91	News agency activities	Not required
63.91.0	News agency activities	Not required
63.99.0	Other information service activities n.e.c.	Not required

The table indicates that there is no license requirement for engaging in IT industry business.

⁴²Order of the Minister of Economy on June 3,2009, N372-U

Dual Use Goods

The legal framework governing dual use goods is established under the Law on Export of Dual Use Goods, Transit through the Territory of the Republic of Armenia. Under the law⁴³ the export of products, information or results of intellectual activities that can be used for military and civilian purposes, i.e. dual use goods - defined as “controlled goods” by law, is restricted and their export and transfer is controlled by the Ministry of Economy. Most of the exports in the High Tech sector appear in the list of the controlled goods. This means that the businesses operating in the given sector must satisfy the procedures established for getting the permit, which is required for exporting such goods.

Procedure for Provision of Permissions for Export and/or Transfer

Export of dual-use goods and technologies must comply with a special procedure⁴⁴ which provides for a permit by the Controlling Committee for Export of Dual Use Goods and Technologies under the Government of Armenia. The list of documents that must be submitted to obtain a permit includes information on the end-user, a technical description of goods, a contract for supply of goods etc.⁴⁵ The permit is issued or denied within 20 days after submission of the required documents.⁴⁶ The State duties are AMD 20,000 for issuing an individual permit and AMD 30,000 for issuing a general permit.⁴⁷

In practice an expert conclusion issued by a specialized agency, the Non-Proliferation Center, may be required before applying for a permit. In order to obtain an expert conclusion the exporter will have to submit a sample of goods, technical specifications, testing reports, documents confirming possession, export documents, a certificate of origin, and a document confirming the classification code.⁴⁸ Expert testing can take up to 10 days and cost as much as AMD 60,000.⁴⁹ The time period of performing the expertise will be established by an expert organization in coordination with the requester of the expertise and should not exceed 10 working days.

⁴³ By law, dual use goods (controlled goods) are goods of any kind, which are used for the civilian purposes and, due to nature and characteristics thereof, may be used for military purposes, including for creation of weapons of mass destruction and means of transportation thereof. Other legal acts establishing regulatory framework of dual use goods include: RA Government Decision N 1785-N of December 15, 2011, RA Government Decision N 924-N of 01.07.2010, RA Government Decision N 765-N of 20.05.2004 are establishing regulatory framework in discussed area

⁴⁴ *Id.*

⁴⁵ Art. 10, Law of the Republic of Armenia on Control of Export and Transit of Dual-Use Goods through the Territory of the Republic of Armenia and Transfer of Dual-Use Information and Products of Intellectual Activity, No. 42, Apr. 8, 2010, O.G. May 5, 2010, No. 18(752)

⁴⁶ *Id.*, art. 10.

⁴⁷ Art. 20, Law on State Duty, *supra* note 141.

⁴⁸ Resolution of the Government of Armenia No. 765, May 20, 2004, O.G. Jun. 16, 2004, No. 31(330).

⁴⁹ *Id.*

The table below presents the specifics of each type of permission

Requirements		Types of permissions	
One-time		Individual	General
Who can apply	Physical persons not having status of individual entrepreneur	Legal persons or private entrepreneurs	Legal persons or private entrepreneurs
Quantity of goods being exported	One (1)	Not limited	Not limited
Quantity of export transactions	One (1)	Not limited	Not limited
Quantity of types of goods being exported	One (1)	One (1)	The types included in commodity positions (groups) are not limited
Quantity of end users	One (1)	One (1)	Not limited
Validity of permission	-	Up to two (2) years, at the applicant's discretion	Up to three (3) years, at the applicant's discretion
Size of state duty for each permission ⁵⁰	Free of charge	Twenty thousand (20,000) Armenian drams	Thirty thousand (30,000) Armenian drams

Application for Obtaining Permission and Documents to be enclosed

To get permission, the exporting entity should apply to the authorized body, the Ministry of Economy, with the following documents to be attached to the application:

- Application, in accordance with the established form;
- Copy of the charter (for legal persons) and copy of state registration certificate (for individual entrepreneurs);
- End-user certificate;
- Technical specifications of goods under control or intangible goods under control;
- Copy of agreement certifying transfer of intangible goods or goods under control;
- Expert opinion or declaration in writing of the exporting entity of goods under control or intangible goods under control;
- In case of submission of application for individual or general permission – receipt for the payment of state duty.

The Government has established cumbersome procedures for obtaining an expert conclusion required in case of the dual use goods. The procedure is both time consuming and costly for businesses. Streamlining of such procedures will benefit the businesses engaged in exporting of goods in the High Tech sector.

⁵⁰ RA law N HO-186 “On State Duty”, 27 December 1997

Recommendations

Streamline procedures entailing expert examination of dual use goods.

INSPECTIONS

The mechanisms of tax administration largely predetermine entrepreneurial activity in Armenia. The Law of the Republic of Armenia “On Organizing and Conducting Inspections in the Republic of Armenia”⁵¹ regulates audits to be conducted by state administration bodies empowered with supervisory powers and administrative competences (ministries, authorities under the government of Armenia, etc.)

The above-mentioned law defines the procedure for conducting audits by state bodies empowered with conducting audits in the Republic of Armenia. In particular, the Law regulates relations in organizing and conducting inspection of business entities’ activity, as well as the unified procedure for conducting such audits.

The Bodies authorized to conduct audits within their competence in the territory of the Republic of Armenia are the following:

- General Department of Civil Aviation
- Ministry of Agriculture
- Ministry of Economy
- Ministry of Education and Science
- Ministry of Energy and Natural Recourses
- Ministry of Finance
- Ministry of Healthcare
- Ministry of Justice
- Ministry of Labor and Social Affairs
- Ministry of Natural Protection
- Ministry of Territorial Administration
- Ministry of Transport and Communication
- Ministry of Urban Development
- National hygiene and Anti-Epidemiological Surveillance Inspectorate
- National inspectorate of Language
- National Security Service
- National Statistic Service
- State Bodies Granting Licenses

- State Committee of Water system of the Ministry of Territorial Administration
- State Fire Inspectorate
- State Labor Inspectorate

⁵¹RA Law N HO-60”On Organizing and Conducting Audits in the Republic of Armenia, 17 May 2000.

- State Nuclear Safety Regulatory committee by the Government
- State Revenue Committee
- The State Commission for the protection of Economic Competition of the RA

State Bodies carrying out audits must act exclusively in compliance with laws of the Republic of Armenia and within the scope of competence envisaged by those laws.

The table below includes the bodies entitled to make inspections in 4 value chains that we are reviewing, according following classifications.

- Main inspecting bodies – MIB;
- Bodies performing time to time inspections – TTI;
- Bodies performing inspections on special occasions – SOI;
- Bodies not related to the sector - NRTS⁵².

#	Auditing bodies	Hospitality	Food processing	Pharmaceutical/ biotechnology	High-Tech
1	Ministry of Justice	NRTS	NRTS	NRTS	NRTS
2	Ministry of Transport and Communication	NRTS	NRTS	NRTS	NRTS
3	Ministry of Natural Protection	NRTS	SOI	SOI	NRTS
4	Ministry of Agriculture	NRTS	SOI	NRTS	NRTS
5	Ministry of Energy and Natural Recourses	NRTS	NRTS	NRTS	NRTS
6	Ministry of Territorial Administration	NRTS	NRTS	NRTS	NRTS
7	State Revenue Committee	MIB	MIB	MIB	MIB
8	State Nuclear Safety Regulatory committee by the Government	NRTS	NRTS	NRTS	NRTS
9	State Fire Inspectorate	TTI	TTI	TTI	TTI
10	National hygiene and Anti-Epidemiological Surveillance Inspectorate	TTI	TTI	TTI	TTI
11	State Labor Inspectorate	TTI	TTI	TTI	TTI
12	Ministry of Finance	NRTS	NRTS	NRTS	NRTS
13	National inspectorate of Language	TTI	TTI	TTI	TTI
14	National Statistic Service	TTI	TTI	TTI	TTI
15	State Committee of	NRTS	NRTS	NRTS	NRTS

⁵² This classification is conditional and expresses the author's approach only.

	Water system of the Ministry of Territorial Administration				
16	National Security Service	SOI	SOI	SOI	SOI
17	Ministry of Economy	MIB	NRTS	NRTS	NRTS
18	Ministry of Healthcare	NRTS	SOI	MIB	NRTS
19	Ministry of Labor and Social Affairs	SOI	SOI	SOI	SOI
20	Ministry of Education and Science	NRTS	NRTS	NRTS	NRTS
21	General Department of Civil Aviation	NRTS	NRTS	NRTS	NRTS
22	The State Commission for the protection of Economic Competition	NRTS	NRTS	SOI	NRTS
23	State Bodies Granting Licenses	TTI	TTI	TTI	TTI
24	Ministry of Urban Development	NRTS	NRTS	NRTS	NRTS

Oftentimes, business entities have to face the following authorities with regard to audits:

- State Revenue Committee under the Government of the Republic of Armenia:
 - State Revenue Committee is entitled, within the powers defined by its charter (<http://www.taxservice.am/Content.aspx?itn=ATSSstatute>) 53, to:
 - in line of tax service:

perform monitoring of compliance with, and enforcement of, requirements of the tax legislation of Armenia and other legal acts regulating tax relations, in accordance with the procedure defined by law;

- in line of customs service:

within its powers, ensure through the system the economic sovereignty, economic security and protection of economic interests of the Republic of Armenia, enforcement of provisions of customs legislation and monitoring of compliance with customs legislation.

- State fire prevention supervisory bodies of the Republic of Armenia⁵⁴:

53Decree N 1005-N of the Government of the Republic of Armenia, 4 September 2008

54Decree N 383-N of the Government of the Republic of Armenia, 10 March 2005

- From October 1, 2010, the State Fire Inspectorate created within the Ministry of Emergency Situations of RA is entitled, within its powers, to:
 - perform monitoring of compliance of state and local administration bodies, organizations, officials and individuals with the requirements of fire security normative documents (http://mes.am/index.php?cat_id=433)
- State Hygienic and Anti-Epidemic Surveillance Service⁵⁵:

Ensure the sanitary and epidemiologic security of Armenia's population, inspection of legal and physical entities' compliance with the requirements of sanitary legislation in Armenia.

The procedures for the 4 value chains' inspections which are the subject for our review are similar and addressed in the Law.

The period of inspection of a business entity should not exceed 15 consecutive working days per year, and the 1st day of inspection should be considered the day when the audit has actually started. The actual day of starting the inspection shall be considered the day when relevant record has been made in the check-up register of the organization. The period of inspection should not exceed the period mentioned in the order (recommendation) on carrying out inspection issued by the head of relevant state authority. On the written substantiation of the official carrying out inspection and by order (recommendation) of the head of relevant state authority the abovementioned period may be suspended for up to 10 uninterrupted working days, if there is necessity, by notifying the head or the deputy head of the business entity under inspection.

Each state authority should inspect the same business entity with the following frequency based on risk level of that entity⁵⁶:

- ✓ High-risk business entity: once a year or less frequently;
- ✓ Medium-risk business entity: once in 3 years or less frequently;
- ✓ Low-risk business entity: once in 5 years or less frequently.

The Government of Armenia established the list of entities, where depending on the danger of type of the economic activity of the entity and its importance for vital interests of the state inspections can be conducted once per 6 months.

Conclusion and Recommendations

Despite the fact that the Law on Inspections clearly defines the duration of audits, in reality it is possible that they might last for months and sometimes longer. The problem is that the audit process may be temporarily suspended based on the auditing body's report (the suspension each

⁵⁵Decree N 1316-N of the Government of the Republic of the Armenia, 15 August 2002

RA Law N HO-60"On Organizing and Conducting Audits in the Republic of Armenia",12 May 2000, Article 2.1

time normally lasts 30 days), after which the audit may be renewed. Therefore, it is recommended to have a strict timeline for the inspections.

The audit manuals and audit methodology should be developed. Currently there are no instructions/manual for the inspectors, based on which the inspections are conducted. It is recommended to develop guidelines and code of ethics for inspectors.

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