



საქართველოს შრომის, ჯანმრთელობისა
და სოციალური დაცვის სამინისტრო
საჯარო სამართლის იურიდიული პირი
სამედიცინო საქმიანობის სახელმწიფო რეგულირების სააგენტო

**MINISTRY OF LABOUR, HEALTH AND SOCIAL
AFFAIRS OF GEORGIA**
Legal Entity of Public Law
State Regulation Agency for Medical Activities



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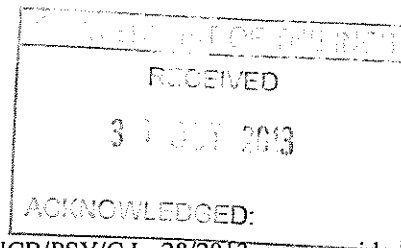
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№ 02/94618

2013 / 10 / 22

To: Secretary of the International Narcotics Control Board
Andres Finguerut



Dear Mr. Finguerut,

In response to your letter of 12 August 2013 - E/INCB/PSY/C.L. 28/2013, we provide you with information on legal measures adopted in Georgia concerning travelers entering/departing the country to carry for their personal use narcotic drugs and psychotropic substances.

The order of the Minister of Labor, Health and Social Affairs of Georgia of 15 June 2011 - N01/32/n regulates the rules for travelers under treatment with narcotic drugs and psychotropic substances when entering/departing the territory of Georgia (see annex 1). We also would like to inform that, apart from internationally controlled narcotic drugs and psychotropic substances, Georgian Law on "Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance", includes the following substances and their dosage forms: Butorphanol, Nalbuphine, Tramadole, Tianeptine, Ketamine, Pregabalin, Fenazepam.

In addition, the order of the Minister of Labor, Health and Social Affairs of Georgia of 22 January 2004 - N 22/n imposes special control measures over combined pharmaceutical products containing narcotic drugs, psychotropic substances, precursors and some psychoactive substances (see annex 2). Refer to annex 3 for the rules concerning travelers under treatment with those combined pharmaceutical products (Article 1¹ of order NI-31 /n).

We also sending you the model form summarizing the above-mentioned information (see. Annex 4).

Sincerely Yours,

Chief of the State Regulation Agency for Medical
Activities

Gia Tvalavadze

Ministry of Labor, Health and Social Affairs of Georgia
Order #01-32/N
June 15, 2011 City of Tbilisi

Regarding approval of procedure for transferring to and from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person

Pursuant to sub-clause "c", article 11¹³ of the Law of Georgia on "Drug and Pharmaceutical Activity", clause 4, article 19 of the Law of Georgia on "Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance" and article 61 of the "Administrative Code of Georgia", hereby I order: (14.03.2013 #01-11/N)

1. To approve
 - a) Procedure for transferring to and from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person (annex #1)
 - b) Form of a document for transferring to and from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person (annex #2).
2. To declare null and void Order # 3/N of January 9, 2004 issued by the Minister of Labor, Health and Social Affairs of Georgia concerning "approval of procedure for carrying of narcotic drugs and psychotropic substances for the needs of a patient in transit through the territory of Georgia".
3. This Order shall become effective upon publication.

Acting Minister

I. Giorgobiani

Procedure for transferring to and from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person

Article 1. Entry into Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person.

1. This article regulates a procedure for introduction into Georgia of narcotic drugs and psychotropic substances being in personal possession for individual needs of a natural person.
2. Entry of narcotic drugs and psychotropic substances as specified under the Law of Georgia on "Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance" (except for psychotropic substances included in the list I of the 1971 Convention on Psychotropic Substances and narcotic drugs included in list IV of 1961 UN Convention on Narcotic Drugs) in a quantity sufficient for 31 days with the purpose of individual needs of a natural person shall be permissible.
3. Carrying from another country into Georgia of narcotic drugs and psychotropic substances being in possession of a natural person for individual needs shall not be regarded as import.
4. In order to bring into Georgia narcotic drugs and/or psychotropic substances purchased in another country by a natural person for individual needs, along with customs declaration the following shall be submitted to the Tax authorities of Georgia: (7.08.2012 #01-49/N)
 - a) Photocopy of the prescription translated into English and certified by an authorized agency according to the rule determined under the laws of that country from where a natural person is traveling. Such prescription shall indicate full name, sex, age of a natural person, diagnosis, brand and generic names of the narcotic drug and/or psychotropic substance, dosage form, quantity of tablets, ampoules, etc, method of administration and duration of treatment (if the prescription form of the given country does not provide for such data, then such data shall be provided in a document as determined under sub-clause "c" of this clause);
 - b) Certificate of a physician issuing prescription translated into English and certified according to the rule established by the laws of the country of departure;
 - c) Document signed and sealed by an authorized person certifying authenticity of the prescription and certificate and issued by a competent authority of the

country of departure. Such document shall indicate a name, juridical address of this authority, contact person, phone number and country of destination.

5. Tax authorities of Georgia shall exercise control over completeness of documents submitted by a patient by examining compliance of types and quantities of narcotic drugs and psychotropic substances indicated in a document specified under clause 4 of this Order with types and quantities of narcotic drugs and psychotropic substances actually carried and in case of compliance, such documents shall be sealed and signed and returned to a natural person.
6. If a foreign national – natural person is unable to leave the territory of Georgia and he/she is out of stock of narcotic drugs and/or psychotropic substances required for treatment, then he/she shall be provided with appropriate medicinal products according to territorial principle (according to a place of temporary residence) and for such purpose a patient shall address a relevant medical institution and submit a document certified by a tax authority that for such institution represents a basis for registering a natural person and prescribing for him/her a narcotic drugs and/or psychotropic substance. Narcotic drugs and/or psychotropic substances shall be prescribed according to a procedure established under the laws of Georgia.
7. A natural person shall be prohibited to transfer narcotic drugs and/or psychotropic substances to other person.
8. Requirement specified under clause 4 of this article shall not apply to narcotic drugs and psychotropic substances remained from the quantity transferred by a citizen of Georgia to a foreign country for individual needs. In such case, a document certified by a tax authority as provided under clause 4, article 2 shall be submitted to the tax authority. (8.11.2011 N01-50/N). F

Article 2. Carrying from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person

1. This article shall regulate a procedure of carrying from Georgia of narcotic drugs and psychotropic substances being in personal possession for individual needs of a natural person.
2. Carrying from Georgia of narcotic drugs and psychotropic substances as specified under the Law of Georgia on "Narcotic Drugs, Psychotropic Substances, Precursors and Narcological assistance" (except for psychotropic substances included in the list I of the 1971 Convention on Psychotropic Substances and narcotic drugs included in list IV of 1961 UN Convention on Narcotic Drugs) with the purpose of individual needs of a natural person shall be permissible.

3. Carrying from the territory of Georgia to the territory of another country of narcotic drugs and psychotropic substances being in possession of a natural person for individual needs shall not be regarded as export.
4. In order to carry from Georgia narcotic drugs and/or psychotropic substances for individual needs, along with customs declaration the following shall be submitted by a natural person to the Tax authorities of Georgia – a document determined under annex 2 of this Order issued by the Legal Entity of Public Law State Regulation Agency for Medical Activities (hereinafter referred to as Agency) being under state control of the Ministry of Labor, Health and Social Affairs of Georgia (7.08.2012 N01-49/N).
5. In order to prepare a document specified under clause 4 of this Article, a natural person or other authorized person shall submit to the Agency:
 - a) Application indicating a country of destination and purpose of travel;
 - b) Health status certificate (medical documentation form N IV-100/A);
 - c) Notarially certified photocopy of the prescription;
 - d) Notarially certified physician's certificate;
 - e) Other documentation as required in a country where a natural person is traveling.
6. Such document shall be completed in English.
7. Such document shall not be issued to a natural person crossing Georgia as transit country (except for cases determined under clause 6 of article 3 of this Order. In such cases, the Agency shall issue a document specified under annex 2 according to a procedure provided under this article).
8. Medical institution where a patient is registered shall prescribe narcotic drugs and/or psychotropic substances in a quantity that is necessary for the period of natural person's stay in a country of destination but such quantity should not exceed the quantity established in such country on which information to the medical institution shall be forwarded by the Agency. It shall be permissible to prescribe for individual needs of a natural person unregistered narcotic drugs and/or psychotropic substances imported to Georgia.
9. Requirement specified under clause 8 of this article shall not apply to narcotic drugs required for substitution treatment of drug addicts. Such natural person may carry from Georgia narcotic drugs for substitution treatment in a quantity required for no more than 4 days and in case of methadone –not exceeding 320 mg.
10. Tax authorities of Georgia shall exercise control over completeness of documents submitted by a patient by examining compliance of types and quantities of narcotic drugs and psychotropic substances indicated in a document specified under clause 4 of this Order with types and quantities of narcotic drugs and

psychotropic substances actually carried and in case of compliance, such documents shall be sealed and signed and returned to a natural person.

11. A natural person shall be prohibited to transfer narcotic drugs and/or psychotropic substances to other person.

Article 3. Transfer to and from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person crossing Georgia as a transit country

1. This article regulates a procedure for transferring to and from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person crossing Georgia as a transit country.

2. Transfer to and from Georgia of narcotic drugs and psychotropic substances as specified under the Law of Georgia on "Narcotic Drugs, Psychotropic Substances, Precursors and Narcological assistance" (except for psychotropic substances included in the list I of the 1971 Convention on Psychotropic Substances and narcotic drugs included in list IV of 1961 UN Convention on Narcotic Drugs) with the purpose of individual needs of a natural person crossing Georgia as a transit country shall be permissible.

3. Transfer to and from Georgia from Georgia of narcotic drugs and psychotropic substances for individual needs of a natural person crossing Georgia as a transit country shall not be regarded as a transit of narcotic drugs and psychotropic substances.

4. In order to carry through Georgia to another country narcotic drugs and/or psychotropic substances purchased in another country by a natural person for individual needs, along with customs declaration the following shall be submitted to the Tax authorities of Georgia: (7.08.2012 #01-49/N)

- a) Photocopy of the prescription translated into English and certified by an authorized agency according to the rule determined under the laws of that country from where a natural person is traveling. Such prescription shall indicate full name, sex, age of a natural person, diagnosis, brand and generic name of the narcotic drugs and/or psychotropic substance, dosage form, quantity of tablets, ampoules, etc, method of administration and duration of treatment (if the prescription form of the given country does not provide for such data, then such data shall be provided in a document as determined under sub-clause "c" of this clause;

- b) Certificate of a physician issuing prescription translated into English and certified according to the rule established by the laws of the country from where a natural person is traveling;

- c) Document signed and sealed by an authorized person certifying authenticity of the prescription and certificate and issued by a competent

authority of the country from where a natural person is traveling. Such document shall indicate a name, juridical address of this authority, contact person, phone and country of destination.

5. Tax authorities of Georgia shall exercise control over completeness of documents submitted by a patient by examining compliance of types and quantities of narcotic drugs and psychotropic substances indicated in a document specified under clause 4 of this Order with types and quantities of narcotic drugs and psychotropic substances actually carried and in case of compliance, such documents shall be sealed and signed and returned to a natural person.
6. If a foreign national – natural person is unable to leave the territory of Georgia and he/she is out of stock of narcotic drugs and/or psychotropic substances required for treatment, then he/she shall be provided with appropriate medicinal products according to territorial principle (according to a place of temporary residence) and for such purpose a patient shall address a relevant medical institution and submit a document certified by a tax authority that for such institution represents a basis for registering a natural person and prescribing for him/her a narcotic drugs and/or psychotropic substance. Narcotic drugs and/or psychotropic substances shall be prescribed according to a procedure established under the laws of FagenGeorgia.
7. A natural person shall be prohibited to transfer narcotic drugs and/or psychotropic substances to other person.

Form of a document of possession of narcotic drugs and psychotropic substances for
a personal use by a natural person leaving Georgia

Name of issuing authority	
Legal address	
Telephone	
Fax	
E-mail	
Date of issue	
Information about natural person	
Last name, first name	
Sex	
Date of birth	
Place of birth	
Home address	
Number of passport or of identity card	
Intended country of destination	

Information about prescribing physician	
Last name, first name	
Home address	
Place of work (name, legal address, telephone, fax, E-mail)	
Number of medical license and date of issue	
Organ of issuing medical license	
Prescribed medical preparation	
Trade/international name of prescribed medical	

preparation	
Dosage form	
Daily dose	
Duration of prescription in days	
Total quantity of medical preparation	

Chief of issuing authority
(Signature and seal)

Customs officer
(Signature and seal)

Labor, Health and Social Affairs of Georgia

Order #22/N

January 22, 2004, City of Tbilisi

Regarding approval of a list of narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances and regulations for their legal circulation

Pursuant to clause 4, article 5 and clause 3, article 31 of the Law of Georgia on “Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance”, hereby I order: (14.03.2013 #01-7/N)

1. To approve a list of narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances (annex #1) and regulations for their legal circulation (annex #2).
2. From the moment of promulgation of this order, the order of the Minister of Labor, Health and Social Affairs #151/N as of July 21, 2003 regarding approval of regulations for legal circulation of combined drugs containing codeine shall become null and void (Georgian legislative herald part III #78, July 31, 2003, article 709).
3. This order shall become effective on the 15th day from the day of its publication.

A. Gamkrelidze

Annex #1 (15.06.2011 #01-30/N shall become effective on the 30th day from the day of its publication.

List of narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances

1. All combined preparations containing ephedrine, norephedrine and pseudoephedrine;
2. Thioridazine (Sonopax);
3. Has been removed (14.03.2013 #01-7/N)
4. Clofeline (only eye drops and ampoules)
5. Combined preparation containing narcotic drugs;
6. Propanidide;
7. Has been removed (14.03.2013 #01-7/N)
8. Chlorpromazine;
9. Ciclodol
10. Has been removed (14.03.2013 #01-7/N)

Note:

- a) This list includes all dosage forms of pharmaceutical products covered by the list with any trade name;
- a) Combined preparation containing narcotic drugs imply those combined medicinal products which with their composition do not belong to the list of narcotic drugs, psychotropic substances and precursors subject to special control in Georgia as specified under the Law of Georgia on "Narcotic Drugs, Psychotropic Substances, Precursors and Narcological Assistance";
- b) The list also includes pharmaceutical products unregistered in Georgia and in case of authorizing on the market of Georgia, the same requirements established under this order shall automatically apply to such pharmaceutical products.

- c) Regulations for legal circulation of narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances as approved under the order

Annex #2 (15.06.2011 #01-30/N shall become effective on the 30th day from the day of publication)

Regulations for legal circulation of narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances

1. Narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances (hereinafter pharmaceutical products) as determined under this Order may be manufactured, imported or exported and sold by a person having authorization for circulation of substances subject to special control.
2. Import and export of medicinal products shall be made on the basis of preliminary agreement document issued by the Legal Entity of Public Law State Regulation Agency for Medical Activities subject to state control of the Ministry of Labor, Health and Social Affairs of Georgia and a permit certificate issued by the same Agency or a Legal Entity of Public Law of the Ministry of Finance of Georgia – Revenue Service (14.03.2012 #01-10/N).
 - 2¹. Placement of pharmaceutical products in the warehouse/terminal using warehouse commodity operation shall be permitted (14.03.2012 #01-10/N).
 - 2². Pharmaceutical products shall be imported to Georgia and placed in the warehouse/terminal using a warehouse commodity operation for the period of the validity of the preliminary agreement document issued by the Agency (14.03.2012 #01-10/N).
 - 2³. Import to Georgia of pharmaceutical products not designed for import and placement in the warehouse/terminal using a warehouse commodity operation shall be made without preliminary agreement and a permit certificate (14.03.2012 #01-10/N).
3. Issuing prescription and retail sale of anesthetics (irrespective of their routes of administration) shall be prohibited.
4. Pharmaceutical products shall be prescribed only through form #2 designed for prescription of non-narcotic pharmaceutical products subject to special control (as approved under Order #465/O issued on November 29, 1999 by the Minister of Labor, Health and Social Affairs of Georgia on approval of prescription forms for issuance of

substances subject to special control, dosage forms of these substances, combined drugs containing such substances and temporary procedures for their prescription). Form #2 prescription number and justification on reasonability for prescription of a medicinal product shall be reordered in the patient's out-patient card.

5. Pharmaceutical products shall be recorded according to types and quantities at the medical and pharmaceutical institutions in a sealed and stamped record-book; a form, rule of making and sealing of such a record-book shall comply with the requirements specified in the Order #150/N as of July 21, 2003 issued by the Minister of Labor, Health and Social Affairs of Georgia regarding "Approval of Rules for Legal Circulation of Narcotic Drugs, Psychotropic Substances and Precursors at Pharmaceutical, Medical, Educational, Scientific-research, Expert-diagnostic and Control-analytical Laboratory, Institutions for the Elderly, People with Disabilities and Children Lacking Care".
6. A pharmaceutical institution shall submit information about circulation of medicinal products according to a rule established by the laws to the Legal Entity of Public Law - State Regulation Agency for Medical Activities subject to state control of the Ministry of Labor, Health and Social Affairs of Georgia (30.12.2011 #01-75/N).

Minister of Labor, Health and Social Affairs of Georgia

Order #01-31/N

June 15, 2011 City of Tbilisi

Regarding determination of quantity of pharmaceutical products to be imported to and exported from Georgia for individual needs of a natural person

Pursuant to sub-clause "c", article 11¹³ of the Law of Georgia on „Drug and Pharmaceutical Activity“ and based on article 61 of the General Administrative Code of Georgia, hereby I order:

1. Import to or export from Georgia of the pharmaceutical products (except for pharmaceutical products subject to special control and the "List of Narcotic Drugs, Psychotropic Substances, Precursors and some) Pharmaceutical Products Containing Psychotropic Substances" (annex #1) as approved by the Order #22/N as of January 22, 2004 issued by the Minister of Labor, Health and Social Affairs of Georgia on "Approval of a list of Narcotic Drugs, Psychotropic Substances, Precursors and some pharmaceutical products containing Psychotropic Substances and Regulations for Their Legal Circulation", including unregistered pharmaceutical products) for individual needs of a natural person shall be determined with the following quantities of the medicinal products: (10.11.2011 #01-53/N)
 - a) Without medical documentation for individual needs of a natural person not more than ten standard packages with respect to drug effect, under his/her personal responsibility;
 - b) If a natural person requires the pharmaceutical product in a quantity exceeding ten standard packages during his/her stay (business trip, treatment, tourism, personal invitation and other) in another country, then import to the country or export from the country of a pharmaceutical product in required quantity shall be made based on appropriate medical documentation, by calculating a daily dose of a medicinal product with consideration of number of days of staying in another country;
 - c) If a natural person being a citizen of Georgia requires more than ten packages of a pharmaceutical product, then import to the country of a pharmaceutical product in a required quantity shall be made based on appropriate medical documentation, by calculating a daily dose of a medicinal product with consideration of a course of treatment;

1¹. Import to Georgia or export from Georgia of the pharmaceutical products included in the “list of narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances” (annex #1) as approved by the Order #22/N as of January 22, 2004 issued by the Minister of Labor, Health and Social Affairs of Georgia on “Approval of a list of narcotic drugs, psychotropic substances, precursors and some pharmaceutical products containing psychoactive substances and regulations for their legal circulation”) for individual needs of a natural person shall be made only based on appropriate medical documentation: (10.11.2011 #01-53/N)

- a) By calculating a daily dose of a pharmaceutical product with consideration of number of days of staying of a natural person in another country (during business trip, treatment, tourism, personal invitation and other);
 - d) In case of a natural person being a citizen of Georgia, by calculating a daily dose of a medicinal product with consideration of a course of treatment;
2. if a pharmaceutical product is imported to Georgia or exported from Georgia via post, pharmaceutical products to be imported or exported shall be subject to confiscation and destruction by the tax authorities:
- a) In case of lack of a primary packaging;
 - b) In case a primary packaging is not intact;
 - c) If it is impossible to establish from the label of a packaging a name of a pharmaceutical product and contained active substances;
 - d) In other cases when a pharmaceutical product has lost its commodity image.
3. Order #247/N as of December 11, 2000 issued by the Minister of Labor, Health and Social affairs of Georgia regarding “determination of quantities of pharmaceutical products for individual needs of a natural person” shall be declared null and void.
4. This order shall become effective upon its publication.

Acting Minister

I. Giorgobiani

GEORGIA (22 October 2013)

Documentation required (i.e. issued/endorsed by medical practitioner or authorized health authority)	Restrictions (i.e. qualitative and/or quantitative)	National Competent Authority (to be contacted for more detailed information) Ministry of Labour, Health and Social Affairs of Georgia
<p>a) Valid medical prescription Copy of medical prescription translated into English and endorsed by competent authority of the country of departure <input checked="" type="checkbox"/></p>	<p>Days / Quantities/Doses</p> <p>Narcotic drugs</p> <p>Also: Butorphanol, Nalbuphine, Tramadol</p> <p><input type="text" value="31 days"/></p>	<p>LEPL "State Regulation Agency for Medical Activities"</p> <p>Address: 144, AK.TSERETELI AVENUE., 0159 TBILISI, GEORGIA</p> <p>Tel: (995 32) 272 50 81</p> <p>Fax: -</p> <p>e-mail: drugcontrol@gol.ge</p>
<p>b) Doctor's certificate endorsed by the health authorities of the country of residence <input checked="" type="checkbox"/></p>	<p>Psychotropic substance</p> <p>Also: Tianeptine, Ketamine, Pregabalin, Fenazepam;</p> <p><input type="text" value="31 days"/></p>	
<p>c) Certificate issued by the health authorities of the country of destination <input type="checkbox"/></p>	<p>List of prohibited substances. if yes, please specify</p> <p>Substances listed in Schedule IV of the 1961 Convention and in Schedule I of the 1971 Convention</p>	
<p>d) Presentation of the original prescription at the Customs of the country of destination <input type="checkbox"/></p>	<p>Other information</p> <p>The appropriate medical documentation is required for: Clophelin (eye drops and ampules), Clorpromazine, Cyclodol (trihexyphenidyl hydrochloride), Propanidide, Thioridazine; Ephedrine/Norephedrine/Pseudoephedrine containing combined preparations and also narcotic drugs containing combined preparations that are not envisaged under the 1961 Convention lists.</p>	
<p>e) Other kind of documents, if yes, please indicate <input checked="" type="checkbox"/></p> <p>Document issued by the competent authority of the country of departure confirming the authenticity of the doctor's certificate and the medical prescription indicating competent authority's name, juridical address, contact person, phone number and country of destination. Document shall also indicate: name, sex, age of a natural person; diagnosis, trade and international names of controlled substances, dosage form, number of units (tablets, ampules, etc.); method of administration and duration of treatment unless this information is provided in the medical prescription.</p>		