

LAW OF GEORGIA ON MEDICINES AND PHARMACEUTICAL ACTIVITIES

This Law establishes a legal framework for the State to ensure the lawful practice of the circulation of pharmaceutical products.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Chapter I – General Provisions

Article 1 - Subject of regulation and scope of application of the Law

1. The legislation of Georgia on medicines and pharmaceutical activities comprises the Constitution of Georgia, international agreements and treaties of Georgia, this Law, and other legislative and subordinate normative acts of Georgia.

2. This Law aims to facilitate the population's increased access to safe pharmaceutical products, and, to ensure this, establishes a legal framework for regulating the circulation of pharmaceutical products and the rights and obligations of natural and legal persons in this field.

3. The state regulation mechanisms provided for by this Law shall be applicable to complementary medicinal products, biologically active additives and para therapeutic products, if an interested person performs the voluntary registration of these products on his/her/its own initiative under the national regime of state registration of pharmaceutical products.

4. Non-invasive contraceptive mechanical devices shall be exempt from the state regulation provided for by this Law.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 1¹ – Definition of terms

1. Generic pharmaceutical product – an international off-patent repeatedly manufactured pharmaceutical product.

1¹. Reference product – a pharmaceutical product used to confirm the bioequivalence of a generic pharmaceutical product, and which has been granted a marketing authorisation for its own market by any regulator recognised by the Government of Georgia, and if there is no such marketing authorisation for the aforementioned market, a reproduced pharmaceutical product having been established on the Georgian market during at least the last 10 years, or an innovative (new original) pharmaceutical product that has been granted a marketing authorisation in Georgia.

2. Bulk pharmaceutical product – a pharmaceutical product that has passed all stages of a manufacturing and technological process, except for the final packaging.

3. Immunobiological preparation – a medicinal product used for immunobiological prevention and therapy (vaccines, sera, test systems, products containing allergens).

4. Patient information leaflet – information that is intended for personnel with medical and pharmaceutical education and/or consumers, and accompanies a pharmaceutical product.

5. Prescription – a note written by a physician to a pharmacist regarding the rules and procedures of preparing, dispensing and administering a pharmaceutical product.

6. Pharmaceutical product prepared according to a magistral formula prescription – a pharmaceutical product prepared for a given patient.

7. Labelling – information presented on a primary and/or secondary packaging.

8. Secondary packaging – a form of packaging, in which a pharmaceutical product that is contained in a primary packaging, is placed.

9. Pharmaceutical product prepared according to an officinal prescription – a pharmaceutical product prepared in a pharmacy according to the pharmacopoeia.

10. Primary packaging – a package form directly covering a pharmaceutical product.

11. Radiopharmaceuticals and diagnostic medical products – preparations with ionising radiation properties and/or chemical products used in medical practice.

12. Medical goods – medical goods used in medical practice for disease prevention, diagnostics, treatment, and patient care: instruments, devices, appliances, medical equipment, dressing material, prosthetic and orthopaedic appliances, etc.

13. Pharmaceutical product (therapeutic agents) – medicine or a physiologically active substances derived naturally or by synthesis, or their combination, allowed for medical use, including complementary medicinal products, biologically active additives and paratherapeutic products that are voluntarily registered under the National Regime of State Registration of Pharmaceutical Products.

13¹. Similar pharmaceutical product – any product of a form and dosage of a medicine, which contains the same active substance (substances) obtained through synthesis or by a biotechnological method (different salt, ether, isomer, or a mix of isomers of the active substance are considered to be the same substance if they do not substantially differ in terms of safety and efficacy).

13². Biological medicinal product – a medicinal product that contains a pharmaceutical substance derived or separated from a biological source. For the purposes of this Law, medicinal products containing active substances of non-transgenic animal or vegetable origin or the sum of these substances, containing active substances derived from human urine, containing bacterial lysates, containing bacteriophages shall not belong to a biological medicinal product. The following shall belong to biological medicinal products:

a) immunobiological preparations;



- b) medicinal products derived from human blood or plasma;
- c) progressive therapy medicinal products. The following belong to them:
 - c.a) gene therapy medicinal products (infectious disease vaccines do not belong to the gene therapy medicinal products):
 - c.a.a) that are used, or introduced into a human body for regulating, restoring, changing, adding or removing genetic sequence, and an active substance of which contains the recombinant nucleic acid or is composed of this acid;
 - c.a.b) therapeutic, preventive or diagnostic action of which is directly connected to the sequence of the recombinant nucleic acid they contain, or to the product of gene expression of such sequence;
 - c.b) somatic cell therapy medicinal products:
 - c.b.a) that contain cells or tissues, or are composed of cells or tissues that have been essentially affected to the extent that significant biological features, physiological functions or structural properties for targeted clinical use have changed, or that contain cells or tissues, or are composed of cells or tissues that are not intended, in the case of a recipient and a donor, for use with the same significant function;
 - c.b.b) that are used, or introduced into a human body for treatment of a disease, prevention or diagnostics due to the pharmacological, immunological or metabolic action which is the result of the properties of cells and tissues contained in them;
 - c.c) tissue engineered medicinal products – medicinal products that contain cells or tissues derived from genetic engineering, or are composed of cells or tissues derived from genetic engineering and that have the ability, when used or introduced into a human body, of human tissue regeneration or replacement;
 - c.d) combined progressive therapy medicinal products – medicinal products that contain one or several medical items, or one or several active implantable medical items that is/are an integral part of a medicinal product and meets/meet one of the following criteria:
 - c.d.a) their cellular or tissue part contains viable cells or tissues;
 - c.d.b) their constituent cellular or tissue part, which contains nonviable cells and tissues, has a prevailing responsibility over a medical item for the impact that this medicinal product has on a human body;
 - d) medicinal products that are derived as a result of one of the following biotechnological processes (for the purposes of this Law, these medicinal products are considered to be the innovative (new original) pharmaceutical products):
 - d.a) recombinant DNA technology;
 - d.b) controlled expression of genes coding biologically active proteins in prokaryotes and eukaryotes, including the transformed cells of mammals;
 - d.c) hybridoma and monoclonal antibody methods.
- 14. Complementary (homeopathic, anthroposophic, homotoxicological) medicinal product – a product prepared from substances or a sum of substances of natural (mineral, plant or animal) origin, the effect and commonality of which has not been proven by objective evidence.
- 15. Biologically active additives (BAA) – a substance used to preserve a physiological state.
- 16. Paratherapeutic product – a product of mineral, plant or animal origin, which has a certain therapeutic effect and which contains a specific medicinal substance in the form and quantity that may be regarded as a form of medicine.
- 17. Efficacy of a pharmaceutical product – a quality indicator of the positive effect of a pharmaceutical product on a clinical course, determined by scientific methods.
- 18. Circulation of a pharmaceutical product – an activity that encompasses preparing, manufacturing, standardisation, controlling quality, packaging, procuring, shipping, storing, selling, providing information on a pharmaceutical product to the population and specialists, advertising, marketing, exporting, importing, re-exporting, using, destroying and other actions related to a pharmaceutical product.
- 19. Raw material – a raw material of any origin which is used, directly or after processing, to prepare a medicine.
- 20. Granting a marketing authorisation for a pharmaceutical product in Georgia – a procedure for determination by an administrative body, of the compliance of a pharmaceutical product with requirements defined by the legislation of Georgia, under which the circulation of a pharmaceutical product in the Georgian market shall be permitted, according to the applicable legislation.
- 21. Wholesale (wholesale distribution) of a pharmaceutical product – operations related to procuring, storage, supply, export, import and re-export of a pharmaceutical product, except for selling directly to a consumer.
- 22. Traceability – the possibility of determining the origin of a pharmaceutical product and/or its ingredients at the manufacturing and distribution stages.
- 23. Pharmaceutical product safety – characteristics based on a comparative analysis of the assessment of the efficacy and damage risk of a pharmaceutical product.
- 24. Agency – a competent agency within the governance of the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia.
- 25. Quality of a pharmaceutical product – an indicator of compliance of identity, quantitative composition, purity, chemical and biological components of a pharmaceutical product with the pharmacopoeia standard.
- 26. Control of a pharmaceutical market – a set of physical, organisational and legal measures for ensuring the compliance with established procedures for the circulation of a pharmaceutical product in the market.
- 27. Departmental registry of pharmaceutical products of Georgia ('the Departmental Registry') – a list of pharmaceutical products that have been granted a marketing authorisation in Georgia, produced by the Agency.
- 28. Minister – the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia.
- 29. Ministry – the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia.
- 30. Batch – a certain quantity of a starting substance and respective adjuvants that are subject to one or more consecutive technological processes in order to achieve their homogeneity.



31. Batch registration – mandatory indication of an identification batch and amount of a purchase and sale subject in documents confirming transactions made at each intermediate state following the distribution, and respectively its registration in an adjacent zone, after passing a relevant administrative procedure for the registration of a pharmaceutical product with the Legal Entity under Public Law - the Revenue Service within the Ministry of Finance of Georgia.
32. Trade licence holder – an owner of a pharmaceutical product that manufactures a pharmaceutical product or has it manufactured to order.
33. Counterfeit pharmaceutical product - a pharmaceutical product deliberately labelled to contain wrong information regarding its identity and/or origin.
34. Random control – an administrative action performed by the Agency, whose frequency and methods used correspond to violation risk assessment.
35. Pharmacological product – a substance or a combination of substances of an established pharmacological activity and safety, which is an object of a clinical trial.
36. Pre-clinical trial of a pharmacological product – a pharmacological, toxicological and other type of study of a pharmacological product to determine its specific activity and the level of impact on the physiological system, which is not conducted on humans.
37. Pharmacopoeia – a collection of standards and regulations defining the quality of a pharmaceutical product.
38. Pharmacopoeial standard (specifications, article, monograph, temporary article in the pharmacopoeia, technical condition) – a document, which contains the quality characteristics of a pharmaceutical product and the methods of analysis to determine these characteristics, which is a basis for quality assessment.
39. Pharmaceutical product seller – a wholesaler or retailer of a pharmaceutical product.
40. Pharmaceutical preparation – a finished dosed pharmaceutical product (including pills, capsules, tablets, ampoules, suppositories, caplets, coated pills, etc.).
41. Pharmaceutical activity – an activity of natural and legal persons engaged in the circulation of pharmaceutical products, as determined by the legislation of Georgia.
42. Pharmaceutical substance – a substance of any origin, of relevant quality and pharmacological activity, which is used for the preparation and/or manufacturing of a pharmaceutical product.
43. Reference standard – a substance in the pharmacopoeia, which has one or more standardised property/properties and is used to assess device calibration, measurement method or substance quality.
44. Active substance – a substance received from a manufacturer, which has one or more standardised property/properties and is used to assess device calibration, measurement method or substance quality.
45. Clinical trial (testing, research) of a pharmaceutical product – the study of the impact of a pharmacological product on a human organism to identify adverse reactions and to assess the efficacy and safety levels.
46. Preparation of a pharmaceutical product – preparing a pharmaceutical product in an authorised pharmacy according to a magistral formula prescription or officinal prescription.
47. Manufacturing of a pharmaceutical product – batch manufacturing of a pharmaceutical product in an enterprise in full compliance with the requirements of an appropriate standard.
48. Pharmaceutical product subject to special control – a narcotic drug, a psychotropic substance and/or a precursor permitted by the legislation of Georgia.
- 48¹. Therapeutic agent equated to a pharmaceutical products under special control – a pharmaceutical product which is not included on the lists of substances under special control, but illegal circulation and abuse of which poses a serious threat to the health of the population, aggravates the situation of narcotic drugs in the country, and which is included on the list approved by an order of the Minister.
- 48². Substandard pharmaceutical product – a therapeutic agent, whose quality index (indices) does (do) not meet the quality standards and specification requirements, considered and assessed by the Agency during the registration process, and/or international standards.
49. Interested person – a manufacturer, a trade licence holder, an importer or any other natural or legal person interested in the marketing authorisation of a product, willing to register a pharmaceutical product under the recognition regime or national regime of state registration of a pharmaceutical product.
50. Recognition of standards and guidelines for pre-clinical and clinical trials of a pharmacological product – the authorisation for use by the Ministry, under the legislation of Georgia, including the international agreements and treaties of Georgia, of international standards, technical regulations and guidelines, on the basis of which pre-clinical and clinical trials of pharmacological products shall be conducted in Georgia.
51. Certificate of quality of a pharmaceutical product – a document confirming the compliance of a pharmaceutical product with the pharmacopoeia standard.
52. Certificate of a Pharmaceutical Product (CPP) – a document confirming the marketing authorisation of a pharmaceutical product in the country, issued by a state body regulating pharmaceutical products in the respective country or internationally.
53. Voluntary registration – non-mandatory registration, permitted only for complementary medicinal products, biologically active additives and paratherapeutic products, registration of which is implemented by an interested person on his/her/its own initiative.
54. First-time import of a pharmaceutical product that has been granted a marketing authorisation in Georgia, but differently packaged and labelled – import, with a different primary and/or secondary packaging and labelling, of a pharmaceutical product that has been granted a marketing authorisation in Georgia under the recognition regime or the national regime of state registration, as well as of a pharmaceutical product registered prior to 15 October 2009 that has been granted a market authorisation in the market under the control of the state body, defined by the Government of Georgia regulating pharmaceutical products in the respective country or internationally.



Corrections - LHG I, No 5, 21.3.2002, p. 11

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 23 of 18 June 2008 - LHG I, No 11, 4.7.2008, Art. 79

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 3806 of 12 November 2010 - LHG I, No 66, 3.12.2010, Art. 414

Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Law of Georgia No 1923 of 23 December 2017 – website, 11.1.2018

Law of Georgia No 3092 of 5 July 2018 – website, 11.7.2018

Law of Georgia No 3402 of 5 September 2018 – website, 25.9.2018

Article 2 - State policy in the field of circulation of pharmaceutical products

The state policy in the field of circulation of pharmaceutical products shall provide for the availability of efficacious, safe and high-quality pharmaceutical products on the Georgian market.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 3 - Role of the State in the circulation of pharmaceutical products

1. The executive authorities shall ensure the enforcement of the legislation of Georgia in the field of circulation of pharmaceutical products and the implementation of the respective state policy.

2. The functions of the Ministry are to:

a) develop a state policy in the field of circulation of pharmaceutical products;

b) establish procedures and conditions for checking the authenticity of a marketing authorisation by the relevant state body regulating pharmaceutical products in the respective country or internationally, of a pharmaceutical product (which has been granted a marketing authorisation in Georgia through the recognition regime of state registration of a pharmaceutical product) in the markets under the control of this body;

c) approve a procedure for keeping, and the format of, a Departmental Registry;

d) determine procedures for the removal/destruction of a pharmaceutical product that has not been granted a marketing authorisation in Georgia, and of a counterfeit, defective, flawed, and expired pharmaceutical product, or to ensure the recognition of technical regulations of another country;

e) in order to ensure the fulfilment of the obligations defined in this Law, develop other relevant legal acts and issue them within the scope of its authority.

3. The functions of the Agency are to:

a) grant a marketing authorisation in Georgia to a pharmaceutical product;

b) perform a random control of a pharmaceutical product;

c) keep a Departmental Registry and ensure its accessibility to the public;

d) issue permits for manufacturing of pharmaceutical products (except for narcotic drugs), clinical trials, an authorised pharmacy, export and import of pharmaceutical products under special control, and control over permit conditions;

e) implement measures to prevent counterfeiting of pharmaceutical products;

f) supervise the destruction/removal of a pharmaceutical product from a distribution network in the case of necessity defined by the legislation of Georgia, keep a register of pharmaceutical product sellers, and perform their random control;

g) issue a document confirming the Georgian market authorisation of a pharmaceutical product;

h) perform other functions defined by the legislation of Georgia.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 23 of 18 June 2008 - LHG I, No 11, 4.7.2008, Art. 79

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Chapter III – Creation and Pharmacological Study of a Pharmaceutical Product

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 4 - Obligation of the Agency to observe the confidentiality and exclusivity of information on a pharmaceutical product

1. The Agency or other body performing administrative procedures shall observe the confidentiality of the information provided by an interested person, which is regarded as a commercial secret under the legislation of Georgia.

2. The Agency shall observe the confidentiality and exclusivity of information on a pharmaceutical product presented for obtaining a permit for granting a marketing authorisation for a pharmaceutical product in Georgia, which implies that a scientific and technical part of documents submitted for the registration of a pharmaceutical product must be confidential and must not be disseminated in the form of public information.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 1923 of 23 December 2017 – website, 11.1.2018

Article 4¹ – General procedure and time limits for observing the confidentiality and exclusivity of information on a pharmaceutical product presented for obtaining a permit for granting a marketing authorisation for a pharmaceutical product in Georgia

1. It shall be prohibited that scientific and technical information on a registered pharmaceutical product be used for making a decision with regard to the registration of the same or similar pharmaceutical product unless a holder of the



right for granting a marketing authorisation for this pharmaceutical product in Georgia consents to the use of the aforementioned information.

2. It shall be prohibited that an applicant for a permit for granting a pharmaceutical marketing authorisation for a pharmaceutical product in Georgia under the national regime of state registration use the test and trial data submitted for registration of the same or similar pharmaceutical product having been granted a marketing authorisation for the first time in any EU member country or Georgia unless a holder of the right for granting the marketing authorisation for this pharmaceutical product consents to the use of the aforementioned data.

3. The procedures established by paragraphs 1 and 2 of this article shall be valid for 6 years after the pharmaceutical product is introduced to the market of any EU member country or Georgia for the first time. This time period may be extended up to 7 years if a basic permit holder obtains, within the first 6 years after obtaining the permit, permission for using a preparation for one or more new therapeutic indications, whichever is considered to have a significant clinical advantage against the existing method of treatment.

Law of Georgia No 1923 of 23 December 2017 – website, 11.1.2018

Article 4² – Liability for non-fulfilment of the obligation to observe the confidentiality and exclusivity of information on a pharmaceutical product

Non-fulfilment of the obligations provided for by Articles 4 and 4¹ of this Law shall entail liability under the legislation of Georgia.

Law of Georgia No 1923 of 23 December 2017 – website, 11.1.2018

Article 5 – Creation of a new pharmaceutical product and funding of a pharmacological study

The creation of a new pharmaceutical product and funding of a pharmacological study shall be unobstructed.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 5¹ – Pre-clinical and clinical trials of a pharmacological product

1. Pre-clinical and clinical trials of a pharmacological product in Georgia shall be performed in accordance with the Standards and Guidelines for the Pre-clinical and Clinical Trials of a Pharmacological Product approved by the Minister.

2. Rights of the sick and healthy volunteers participating in a trial shall be protected by the legislation of Georgia.

3. Before commencing a clinical trial, a sponsor (a person, a company, an institution, or an organisation responsible for the commencement, management and/or financing of a clinical trial) shall provide clinical trial risk/responsibility insurance for as long as the clinical trial period, which includes payment and/or compensation for the treatment expenses of a person/persons (that he/she/they needed/will need for participation in a clinical trial) participating in the clinical trial.

4. The following clinical trials shall be allowed to be performed on a health volunteer in Georgia:

a) a bioequivalence trial of a medicinal product;

b) a pharmacokinetic trial of a pharmacological product developed in Georgia;

c) a trial, recognised by the legislation of Georgia, allowed in a market subject to the control of a foreign or interstate state authority regulating pharmaceutical products, which are performed on a healthy volunteer.

5. A clinical trial of a pharmacological product intended for use as a progressive therapy medicinal product may only be performed if the pharmacological product is manufactured according to any GMP standard recognised by the Government of Georgia in an enterprise having the authority to manufacture a biological medicinal product.

6. Clinical trials may not be performed in Georgia using the products and agents defined by Article 1¹(48) and (48¹) of this Law.

Law of Georgia No 3402 of 5 September 2018 – website, 25.9.2018

Article 6 - (Invalid)

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 7 - (Invalid)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 8 - (Invalid)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Chapter IV – State Control of Pharmaceutical Product Safety

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 9 – Objective of the state control of pharmaceutical product safety

The objective of state control of pharmaceutical product safety shall be to protect the Georgian market from a counterfeit,



defective, flawed, and expired pharmaceutical product, dangerous for a consumer, and a pharmaceutical product that has not been granted a marketing authorisation in Georgia.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 10 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Article 10¹ - Measures to be implemented by the State to ensure pharmaceutical product safety

In order to ensure pharmaceutical product safety, the State shall implement the following measures:

- a) grant a marketing authorisation in Georgia to a pharmaceutical product;
- b) issue a permit for manufacturing a pharmaceutical product;
- c) issue a permit for a clinical trial of a pharmacological product;
- d) issue a permit for an authorised pharmacy;
- e) issue a permit for export or import of pharmaceutical products under special control;
- f) ensure the possibility of performing system control of the registration of a pharmaceutical product batch;
- g) keep a register of pharmaceutical product sellers;
- h) perform random control of pharmaceutical product sellers.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 11 - Random control

1. The Agency shall be obliged to perform random control of pharmaceutical product sellers based on risk assessment.
2. During random control, the Agency may check the status of the compliance by pharmaceutical product sellers with established procedures for traceability of a pharmaceutical product and with storage conditions.
3. In the cases provided for by the legislation of Georgia, for random control purposes, the Agency may procure a pharmaceutical product from pharmaceutical product sellers for further laboratory trials.
4. The Ministry shall approve or ensure the recognition of a manual for random control (technical regulations, and guidelines containing procedures and terms for conducting random control, including procuring samples), based on risk assessment.

Law of Georgia No 713 of 28 December 2000 - LHG I, No 1, 16.01.2001, Art. 1

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 23 of 18 June 2008 - LHG I, No 11, 4.7.2008, Art. 79

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 11¹ - Control and supervision of a pharmaceutical market

1. In order to perform random control of a pharmaceutical product, based on risk assessment, the Agency shall use the mechanisms of laboratory control and administrative control of a distribution chain.
2. The Agency shall mainly use the mechanism of administrative control of a distribution chain to control and supervise a pharmaceutical product available on the Georgian market.
3. The mechanism of laboratory control shall be used in the case of high risk of counterfeiting and spoilage (the Minister shall approve risk criteria) of a pharmaceutical product that has been granted marketing authorisation under the national regime and recognition regime of state registration of a pharmaceutical product.
4. In particular cases, the Agency shall enjoy discretionary powers not to take into account formal criteria defining the risk, and to use the mechanism of laboratory control, but such cases should not exceed 10 percent of the inspection frequency during one year.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 11² - Grouping of pharmaceutical products for advertising and retailing purposes

1. For advertising and retailing purposes, pharmaceutical products shall be divided into 3 groups:
 - a) the first group shall include pharmaceutical products under special control, as well as therapeutic agents equated with pharmaceutical products under special control in terms of a legitimate circulation regime (the Minister shall approve the list of therapeutic agents equated with pharmaceutical products under special control and the procedure for their legal circulation);
 - b) the second group shall include pharmaceutical products, whose inappropriate use may cause considerable damage to human health and life, and/or which may not be administered according to the patient information leaflet only, without a physician's prescription, and which are dispensed on prescription (the Minister shall determine the procedure for writing a prescription for a pharmaceutical product falling under the second group);
 - c) the third group shall include pharmaceutical products that may be administered according to the patient information leaflet without a physician's prescription, and that are dispensed over the counter.
2. Assigning pharmaceutical products having the same generic name, form and dosage but different brand names to more than one group shall be inadmissible.
3. The Minister shall define the lists of pharmaceutical products falling under the first and third groups referred to in



paragraph 1 of this article.

4. Pharmaceutical products falling under the third group shall be defined on the basis of international practice. All other pharmaceutical products that have been granted marketing authorisation in Georgia shall automatically fall under the second group.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 11³ - Advertising a pharmaceutical product

1. Advertising of a pharmaceutical product shall mean dissemination of material in the mass media, or in any other form and by any other means, and/or an action that aims to promote the use of this pharmaceutical product.

2. It shall be prohibited to advertise pharmaceutical products subject to special control (falling under the first group), pharmaceutical products falling under the second group, and those that have not been granted marketing authorisation in Georgia.

3. Pharmaceutical products falling under the third group may be advertised subject to prior coordination of an advertising text with the Agency and the compliance with the following conditions:

a) if a pharmaceutical product is advertised in printed form, it must contain the warning: 'Read the patient information leaflet before use, and consult your doctor for further information on side effects';

b) if a pharmaceutical product is advertised in non-printed form, the warning must be in verbal form;

c) if a pharmaceutical product is advertised on television, where the advertisement can be both seen and heard, the warning text must be visible (legible) for not less than 3 seconds and it must also be in verbal form.

4. Prior coordination of an advertisement text with the Agency shall imply agreement as to the advertisement text corresponding to the information stated in the patient information leaflet.

5. An advertisement text of a pharmaceutical product may not differ in content from the indications of this product included in the patient information leaflet.

6. Indicating diseases in an advertisement text of complementary medicinal products, biologically active additives and paratherapeutic products that have not been registered as pharmaceutical products, or have not been voluntarily registered under the national regime of state registration of a pharmaceutical product, and presenting such products as pharmaceutical products shall be inadmissible.

7. Advertising of a pharmaceutical product voluntarily registered under the national regime of state registration of a pharmaceutical product shall be free, and the regulation provided for by this article shall not be applicable to such a pharmaceutical product, except for the regulation defined in paragraph 5 of this article.

8. The Agency shall monitor advertising of a pharmaceutical product to ensure compliance with the conditions determined by this Law.

9. The following shall not be considered as advertising:

a) labelling and a patient information leaflet of a pharmaceutical product;

b) business correspondence;

c) flyers and reference material of factual and informative nature, if the information presented in them refers only to changes of a pharmaceutical product and/or precautionary measures;

d) information related to health and/or a disease, if it does not contain a direct or indirect reference to treatment using the pharmaceutical product;

e) providing information on a pharmaceutical product to medical and pharmaceutical personnel.

10. Pharmaceutical products falling under the first and second groups, as well as pharmaceutical products that have not been granted marketing authorisation in Georgia may not be distributed to the population for advertising purposes.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 11⁴ - Regimes for granting marketing authorisation in Georgia to a pharmaceutical product

1. Marketing authorisation shall be granted to a pharmaceutical product under the following regimes:

a) the recognition regime of state registration of a pharmaceutical product;

b) the national regime of state registration of a pharmaceutical product.

2. The grounds for using the recognition regime of state registration of a pharmaceutical product shall be the differentiation of a state body regulating pharmaceutical products in a foreign country or internationally in terms of reliability and granting a market authorisation to only high quality pharmaceutical products in markets under the control of this body.

3. Georgia shall unilaterally recognise safety, efficacy, and quality requirements for granting market authorisation to a pharmaceutical product in markets under the control of this body, set by a state body regulating pharmaceutical products in a foreign country or internationally. Georgia shall not carry out a repeated expertise with regard to the above or similar requirements in order to determine the safety, quality and therapeutic efficacy of a pharmaceutical product.

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Article 11⁵ - Validity period of marketing authorisation of a pharmaceutical product in Georgia

1. The validity period of marketing authorisation of a pharmaceutical product in Georgia shall be defined under the recognition regime and national regime of state registration of a pharmaceutical product.

2. After expiry of marketing authorisation in Georgian, the circulation of a pharmaceutical product, except for its import, shall be admissible up to expiry of the shelf life of pharmaceutical products already in circulation on the territory of Georgia.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149



Article 11⁶ - Departmental Registry

1. Entry of a pharmaceutical product into the Departmental Registry shall imply granting marketing authorisation in Georgia to a pharmaceutical product.
 2. The Departmental Registry shall specify a registration number, an interested person, a manufacturing country, a brand name, an international off-patent name (if any), a form, a dosage, if necessary - a concentration, a registration date, registration validity period and an electronic version of a packaging and labelling sample.
 3. The Departmental Registry shall be a public document. For the purpose of unobstructed access of the public to the information, the Departmental Registry shall be kept in an electronic form and shall be made accessible through the internet.
 4. Under the recognition regime of state registration of a pharmaceutical product, a pharmaceutical product may be entered in the Departmental Registry:
 - a) proactively by the Agency, on the basis of the information on a pharmaceutical product that has been granted marketing authorisation in the respective market by a state body regulating pharmaceutical products in a foreign country or internationally;
 - b) after an administrative review of homology identification documents defined in Article 11¹⁰ of this Law, which are submitted by an interested person;
 - c) after the procedure of notification by an interested person about the first-time import of a pharmaceutical product that has been granted marketing authorisation in Georgia, but differently packaged and labelled.
 5. A pharmaceutical product shall be entered in the Departmental Registry, under the national regime of state registration of a pharmaceutical product, after completion of the procedure determined by Article 11¹¹ of this Law.
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Article 11⁷ - Recognition regime of state registration of a pharmaceutical product

1. The recognition regime of state registration of a pharmaceutical product shall be applicable to a pharmaceutical product that has been granted marketing authorisation in the respective market by a state body regulating pharmaceutical products in a foreign country or internationally.
2. The Government of Georgia shall compile a list of state bodies regulating pharmaceutical products in foreign countries or internationally for the purpose of recognising pharmaceutical products registered by them.
3. Any person may be an interested person during the state registration of a pharmaceutical product through the recognition regime.
4. An interested person may go through the procedure, provided for by this Law, to obtain a marketing authorisation in Georgia for a pharmaceutical product under the recognition regime of state registration of a pharmaceutical product, irrespective of the purpose of import.
- 4¹. Progressive therapy medicinal products may be introduced in the pharmaceutical market of Georgia under the recognition regime of state registration of a pharmaceutical product. Furthermore, medicinal products of progressive therapy and/or those classified as one of its type may be introduced in the aforementioned market if they have been allowed by the Government of Georgia in a market subject to the control of a foreign or interstate state authority regulating pharmaceutical products.
5. When importing a pharmaceutical product under the recognition regime of state registration of a pharmaceutical product for the first time, an interested person shall submit the following homology identification documents:
 - a) an authorised translation of a patient information leaflet in the Georgian language and the original patient information leaflet, under the procedure established by the Ministry;
 - b) the following information on a pharmaceutical product:
 - b.a) the form;
 - b.b) the dosage;
 - b.c) a labelling sample, which may be submitted in the original or an electronic form; the Agency shall enjoy discretionary power regarding the form of requiring a labelling sample; at the same time, if a pharmaceutical product has not been put into production, the Agency shall be obliged to accept an electronic version of a labelling sample. After a pharmaceutical product is put into production, the Agency may request to replace an electronic version of a labelling sample with a sample in material form;
 - b.d) a reference standard in the quantity sufficient to conduct 2 tests (an interested person may submit an active substance of the respective pharmaceutical product instead of a reference standard);
 - c) the validity period of marketing authorisation in the respective market granted by a state body regulating pharmaceutical products in a foreign country or internationally;
 - d) a unique number of the marketing authorisation of a pharmaceutical product in the respective market;
 - e) a Certificate of a Pharmaceutical Product (CPP) issued by a state body regulating pharmaceutical products in a foreign country or internationally, which may have been issued for any market under the control of a state body regulating pharmaceutical products in a foreign country or internationally, recognised by the Government of Georgia;
 - f) instead of a CPP referred to in paragraph 5 (e), a document equivalent to a CPP may be submitted, which may have been issued for any market under the control of a state body regulating pharmaceutical products in a foreign country or internationally, recognised by the Government of Georgia. Duly attested copies of a CPP or a document equivalent to the CPP may be submitted;
 - g) analysis methods that may be printed from a publicly available source (the pharmacopoeia), with reference to the source;
 - h) a sample of a pharmaceutical product - 2 standard packages or a quantity sufficient to conduct 2 tests.



6. If any document provided for by paragraph 5 of this article contains other information required for homology identification documents, this information need not be submitted in a separate document.
 7. The Agency shall perform an administrative review of homology identification documents and, within seven working days, shall enter the information on a pharmaceutical product into the Departmental Registry.
 8. The period of a marketing authorisation in Georgia granted to a pharmaceutical product registered under the recognition regime of state registration shall be determined as per the period of marketing authorisation granted in a market subject to the control of a foreign or interstate state authority regulating pharmaceutical products but for not more than 5 years.
- Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149*
Law of Georgia No 2560 of 12 February 2010 - LHG I, No 6, 22.2.2010, Art. 21
Law of Georgia No 3402 of 5 September 2018 – website, 25.9.2018

Article 11⁸ - Obligation of an interested person to notify about the first-time import of a pharmaceutical product that has been granted marketing authorisation in Georgia, but is differently packaged and labelled

1. The first-time import of a pharmaceutical product that has been granted marketing authorisation in Georgia, but that is differently packaged and labelled, need not be re-registered. Such a pharmaceutical product shall be granted marketing authorisation in Georgia based on the notification procedure provided for by this article.
2. The notification shall contain the following information:
 - a) an authorised translation of a patient information leaflet in the Georgian language and an original patient information leaflet, under the procedure established by the Ministry;
 - b) a packaging and labelling sample of a pharmaceutical product in an electronic form;
 - c) a certificate issued by a person authorised to sell a pharmaceutical product in the respective country, which confirms marketing authorisation of a pharmaceutical product with given packaging and labelling granted by a state body regulating pharmaceutical products in a foreign country or internationally in the market under the control of this body. The certificate shall be accompanied by the identification information of a person authorised to sell the pharmaceutical product;
 - d) a unique number of the marketing authorisation of a pharmaceutical product in the respective market.
3. After receiving a notification:
 - a) the Agency shall be obliged to check the information submitted by an interested person;
 - b) considering factual circumstances only, the Agency may reasonably refuse the first-time import of a pharmaceutical product that has been granted marketing authorisation in Georgia, but that is differently packaged and labelled, and give a written notice to the interested person;
 - c) failure to respond shall automatically mean the consent of the Agency to the first-time import of a pharmaceutical product that has been granted marketing authorisation in Georgia, but that is differently packaged and labelled.
4. In case of consent, the Agency shall be obliged, within five working days after receipt of notification, to enter into the Departmental Registry the information on a pharmaceutical product that has been granted marketing authorisation in Georgia, but that is differently packaged and labelled.

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Article 11⁹ - Obligation of an interested person during the period of circulation of a pharmaceutical product in the Georgian market

1. During the period of circulation of a pharmaceutical product in the Georgian market, an interested person shall be obliged to keep:
 - a) a batch certificate of quality;
 - b) a batch number of a pharmaceutical product.
 2. The documents referred to in paragraph 1 of this article shall be kept by an interested person during the period of owning a pharmaceutical product by him/her/it.
 3. After transfer of a pharmaceutical product to another person, the responsibility for fulfilling the obligation provided for by this article shall rest with the person who directly owns the pharmaceutical product before selling it.
- Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149*

Article 11¹⁰ - Checking the homology identification documents

1. After receiving homology identification documents from an interested person, the Agency may check the submitted documents, and deliver copies to a person authorised to represent the branch (permanent establishment) of an enterprise of the respective foreign country, which is registered under the legislation of Georgia, without reference to the information containing a commercial secret.
2. The Agency shall be obliged to deliver the copies provided for by paragraph 1 of this article, upon request, to a person authorised to represent the branch (permanent establishment) of an enterprise of a foreign country.
3. A person authorised to represent the branch (permanent establishment) of an enterprise of a foreign country may check the received documents, and in the case of doubt regarding the origin and quality of a pharmaceutical product, shall notify the Agency.
4. In the case of receiving of a notification from a person authorised to represent the branch (permanent establishment) of an enterprise of a foreign country, the Agency shall be obliged to check this information and, if the doubt is confirmed, shall take measures defined by the legislation of Georgia.
5. After it has checked the homology identification documents, the Agency shall enter the information on a pharmaceutical product into the Departmental Registry.
6. The Agency shall be obliged to revoke the registration of a pharmaceutical product in the case of expiry of the



Article 11¹¹ - National regime of state registration of a pharmaceutical product

1. The state registration of a pharmaceutical product through the national regime shall be implemented in the following manner:
 - a) A person interested in the state registration of a pharmaceutical product through the national regime may be a manufacturer of a pharmaceutical product or a trade licence holder. An interested person shall submit an application and the attached documents to the Agency. An application shall meet the requirements of Article 78 of the General Administrative Code of Georgia.
 - b) Registration documents shall consist of administrative and scientific-and-technical parts. The Agency shall conduct the administrative and scientific and technical review of the parts.
 - c) The administrative part of the registration documents shall be submitted in a tangible form in the Georgian language (an electronic version of the Georgian translation of the manual, in Word format and on a CD, and a sample of packing and marking of a pharmaceutical product shall be submitted along with the tangible form), while the scientific and technical part shall be submitted in the Georgian, Russian and English languages in three identical copies (the interested persons shall be responsible for the identity of copies), in an electronic form on a CD, on which the following information must be specified: the trade name of a pharmaceutical product, the manufacturer, the trade licence holder (if any), the form and dosage of a medication, the quantity of the pharmaceutical product in a package, the registration regime of a pharmaceutical product, the date when the administrative part and the scientific and technical part of the registration documents are submitted;
 - d) Not later than 14 days after receipt of registration documents, the Agency shall check their compliance with the requirements of this article, i.e. shall conduct their administrative review.
 - e) Based on positive conclusions of an administrative review, registration documents shall be subject to further scientific and technical review for the purpose of standardisation of a pharmaceutical product and determining its quality, safety and therapeutic efficacy.
 - f) In order to eliminate inaccuracy identified at the administrative or scientific and technical review level, an interested person shall be given an additional time frame of up to two months. If an interested person fails to correct the flaw within that time, the registration document shall remain unconsidered.
 - g) If necessary, the Agency may additionally involve experts in the consideration of registration documents, who shall bear responsibility for the impartiality of their opinion.
2. Changes to active substances, a form, efficacy (dosage, concentration), method (mode) of administration, and manufacturing of a pharmaceutical product shall be deemed as Type-II variations (of significant importance) and shall be subject to registration.
3. The variations referred to in paragraph 21 of this article shall be deemed as Type-I variations (of comparatively less significant importance) and the information regarding such variations shall be subject to be submitted to the Agency.
4. If the conditions referred to in paragraph 3 of this article are not met, such variations shall be shifted to Type-II variations and shall be subject to registration.
5. In the case of Type-I and Type-II variations:
 - a) the following shall be submitted:
 - a.a) motivation for a variation
 - a.b) documents confirming the variation
 - a.c) updated registration documents
 - b) the registration of a variation shall not entail change of the registration validity period.
6. For the re-registration of a pharmaceutical product, registration documents shall be submitted not later than two months prior to expiry of the registration validity period. Otherwise, a pharmaceutical product shall be registered under the primary registration regime.
7. When re-registering a pharmaceutical product, an interested person shall submit the documents provided for by paragraph 19 of this article, and the data on the side effects of the pharmaceutical product for at least 4 years out of the 5-year period of the last marketing authorisation it was granted, the publications and bibliography, the current edition of the specification compliant with the requirements of the sets of international standards for a medicinal product and the methods of analysis, and attach a document evidencing payment of the registration fee.
8. The time frame of a registration procedure, including re-registration, registration of a variation, registration and entry in the register, shall be counted from the date of submission of a complete set of registration documents.
9. During the registration procedure, the Agency shall decide to register or refuse to register a pharmaceutical product or a variation within three months in the case of registration of a Type-II variation, within two months - in the case of re-registration or registration and entry in the register of a pharmaceutical product, within 10 days - in the case of registration of a Type-IA variation, and within one month - in the case of registration of a Type-IB variation, which shall be documented in an administrative act.
10. If the Agency refuses to register a pharmaceutical product, it shall be obliged to immediately give a written notice of a reasonable refusal to an interested person. If an interested person is not notified about the decision not to register a pharmaceutical product within the time referred to in paragraphs 1(d) and 9 of this article, a pharmaceutical product shall be considered as registered, and the Agency shall be obliged to issue a document confirming marketing authorisation in Georgia. A document certifying marketing authorisation shall be formalised within 10 days after issuing an administrative act regarding the registration. An administrative act and a document certifying the marketing authorisation in Georgia shall be equivalent documents.
11. If a pharmaceutical product has not been put into production, the Agency shall be obliged to accept an electronic



version of a labelling sample. After a pharmaceutical product is put into production, the Agency may request to replace an electronic version of a labelling sample with a sample in material form.

12. The Agency shall revoke the registration of a pharmaceutical product in Georgia:

- a) upon request of an interested person;
- b) if a pharmaceutical product appeared to be harmful to humans or their descendants.

13. The Agency shall temporarily suspend the registration of a pharmaceutical product in Georgia until the cause of suspension is eliminated:

- a) upon request of an interested person;
- b) if any part of registration documents changes, which has not been registered and/or entered in the register under an established procedure and form.

14. The Agency shall revoke a document confirming marketing authorisation in Georgia:

- a) if the registration of the pharmaceutical product has been revoked;
- b) in the case of necessity of issuing a new document certifying marketing authorisation.

15. Expiry of the registration validity period shall entail revoking a document certifying marketing authorisation in Georgia.

16. A pharmaceutical product may be circulated on the territory of Georgia for five years after its registration, and after expiry of the registration validity period - up to expiry of the shelf life of the pharmaceutical product.

17. In case of variations, a pharmaceutical product available prior to variations introduced may be circulated on the territory of Georgia up to expiry of its shelf life.

18. A pharmaceutical substance, bulk and intermediary pharmaceutical products, pharmaceutical products prepared according to magistral formula prescription and officinal prescription, and allergens designated for an individual natural person shall not be subject to registration.

19. The administrative part of registration documents shall include:

- a) an application accompanied with a check-list of attached documents (with an indication of page numbers);
- b) an original application for the registration of a pharmaceutical product in Georgia under the national regime of state registration of a pharmaceutical product;
- c) an original document confirming granting by an interested person representative authority to a natural or legal person;
- d) a (original) CPP in the form recommended by the World Health Organization, and if it is not available – a document certifying that the pharmaceutical product has been manufactured according to the GMP (Good Manufacturing Practices) standard, or a pharmaceutical product manufacturing licence issued by an authorised body of the manufacturing country. In the case of dental material, an invasive mechanic means of contraception, or means of diagnostics, an ISO certificate or an EC certificate of the product manufacturer, or a free sale certificate may be submitted;
- e) a standard packaging with standard labelling (or an electronic version) of a pharmaceutical product to be registered;
- f) in the case of registration of a pharmaceutical product manufactured in Georgia, a patient information leaflet in the Georgian language, and in the case of registration of an imported pharmaceutical product, an authorised (attested) translation of a patient information leaflet (information, which accompanies the pharmaceutical product, intended for both personnel with medical and pharmaceutical education, and for customers, if there are differential versions of the patient information leaflet) into the Georgian language and an original patient information leaflet, under procedures established by the Ministry;
- g) a document evidencing payment of the registration fee.

20. The following shall be presented under the scientific and technical part of registration documents:

a) for the registration of an innovative (new original) pharmaceutical product:

- a.a) a document confirming the registration of a pharmaceutical product in a manufacturing country, as well as in other countries (if any);
- a.b) the chemical composition of a pharmaceutical product, with an indication of all its ingredients and quantity of ingredients in a dose unit;
- a.c) monographs about an active substance (substances) (specifications and methods of analysis);
- a.d) the name and address of a manufacturer (manufacturers) of an active substance (substances) and bulk pharmaceutical products;
- a.e) monographs or references to the monographs, that are available in international collections of standards, about an inactive substance (substances) (specifications and methods of analysis);
- a.f) monographs about the methods of analysis of a pharmaceutical products, including specifications;
- a.g) a manufacturing process flow chart of a pharmaceutical product;
- a.h) a pharmaceutical product sample - 2 standard packages plus a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;
- a.i) a reference standard (reference standards) in a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;
- a.j) data on the stability of a pharmaceutical product;
- a.k) pre-clinical trial data on a specific pharmacological activity of a pharmaceutical product, in particular:
 - a.k.a) pharmacodynamic effect;
 - a.k.b) mechanism of action;
 - a.l) pharmacokinetic study data;
 - a.m) toxicological study data on acute, sub-acute and chronic toxicity;
 - a.n) data on teratogenicity, embryotoxicity, mutagenicity, carcinogenicity and allergenicity;
 - a.o) clinical data on pharmacokinetics, pharmacodynamics and side effects;
 - a.p) a report on clinical trials of the pharmaceutical product;
 - a.q) summarised data on side effects;



a.r) experience on the clinical use of the pharmaceutical product:

a.r.a) interaction with other pharmaceutical products;

a.r.b) publications and bibliography;

Note: For the purposes of this Law, new combinations, a new medication form or a new effect of generic medicinal products, which have not been granted authorisation by a foreign or interstate state authority, defined by the Government of Georgia, regulating pharmaceutical products, for a market subject to its control, shall be considered innovative (new original) pharmaceutical products. They shall be granted authorisation for the Georgian pharmaceutical market under sub-paragraph a) of this paragraph. Furthermore, it shall be permissible that the data according to appropriate recommendations of the World Health Organisation or other internationally recognised guidelines be submitted instead of all data provided for by sub-paragraphs (a.k-a.r.a) of this paragraph.

b) for the registration of a generic and repeatedly manufactured pharmaceutical product:

b.a) a chemical composition of a pharmaceutical product, with an indication of all its ingredients and quantity of ingredients in a dose unit;

b.b) an appropriate document regarding the right to repeatedly manufacture a pharmaceutical product under a licence (if any);

b.c) monographs or references to the monographs, that are available in international collections of standards, about an active substance (substances) (specifications and methods of analysis);

b.d) name and address of a manufacturer (manufacturers) of an active substance (substances);

b.e) monographs or references to monographs, that are available in international collections of standards, about an inactive substance (substances) (specifications and methods of analysis);

b.f) monographs about the methods of analysis of a pharmaceutical products, including specifications;

b.g) a pharmaceutical product manufacturing process flow chart;

b.h) a pharmaceutical product sample - 2 standard packages plus a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;

b.i) a reference standard (reference standards) in a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;

b.j) data on the stability of the pharmaceutical product;

b.k) data on bioequivalence or therapeutic equivalence, considering the form and mode of administration of the pharmaceutical product (according to the recommendations of the World Health Organisation);

b.l) publications and bibliography;

c) for the registration of a blood preparation:

c.a) a document confirming the registration of a blood preparation in a manufacturing country, as well as in other countries (if any);

c.b) a chemical composition of a blood preparation, with an indication of all its ingredients and quantity of ingredients in a dose unit;

c.c) monographs or references to monographs that are available in international collections of standards, about an active substance (substances) (specifications and methods of analysis);

c.d) name and address of a manufacturer (manufacturers) of an active substance (substances);

c.e) monographs or references to monographs that are available in international collections of standards, about an inactive substance (substances) (specifications and methods of analysis);

c.f) monographs about the methods of analysis of a blood preparation, including specifications;

c.g) a blood preparation manufacturing process flow chart;

c.h) a blood preparation sample - 2 standard packages plus a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality attested by an authorised body;

c.i) a reference standard (reference standards) in a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;

c.j) data on the stability of a blood preparation;

c.k) description of a sealed container system;

c.l) data on the efficacy and safety of a blood preparation (in the format recommended by the World Health Organisation), with a description of the methods of inactivation of viruses;

c.m) publications and bibliography;

d) for the registration of an immunobiological preparation:

d.a) a document confirming the registration of an immunobiological preparation in a manufacturing country, as well as in other countries (if any);

d.b) a method of deriving and material of an immunobiological preparation, the name and address of a manufacturer (manufacturers);

d.c) monographs or references to monographs that are available in international collections of standards, about an active substance (substances) (specifications and methods of analysis);

d.d) monographs about the methods of analysis of an immunobiological preparation, including specifications;

d.e) an immunobiological preparation manufacturing process flow chart;

d.f) an immunobiological preparation sample - 2 standard packages plus a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;

d.g) data on the stability of an immunobiological preparation;

d.h) clinical data on the efficacy, safety and side effects of an immunobiological preparation;

d.i) interaction with other pharmaceutical products;

d.j) publications and bibliography;

e) for the registration of a paratherapeutic product:



- e.a) a chemical composition of a paratherapeutic product, with an indication of all its ingredients and quantity of ingredients in a dose unit;
- e.b) monographs about active substances (specifications and methods of analysis);
- e.c) the name and address of a manufacturer (manufacturers) of an active substance (substances);
- e.d) monographs or references to monographs that are available in international collections of standards, about an inactive substance (substances) (specifications and methods of analysis);
- e.e) monographs about the methods of analysis of the para therapeutic product, including specifications;
- e.f) a paratherapeutic product manufacturing process flow chart;
- e.g) data on the stability of a paratherapeutic product;
- e.h) a paratherapeutic product sample - 2 standard packages plus a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;
- e.i) a reference standard (reference standards) (if necessary) in a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;
- e.j) data on the safety and efficacy of a para therapeutic product;
- f) for the registration of a radiopharmaceutical:
 - f.a) a document confirming the registration of a radiopharmaceutical in a manufacturing country, as well as in other countries (if any);
 - f.b) a chemical composition of a radiopharmaceutical, with an indication of all its ingredients, quantity of ingredients in a dose unit, their specific or relative activity;
 - f.c) monographs about an active substance (substances) (specifications and methods of analysis);
 - f.d) a method of deriving of an active substance (substances), the name and address of a manufacturer (manufacturers);
 - f.e) monographs or references to monographs that are available in international collections of standards, about an inactive substance (substances) (specifications and methods of analysis);
 - f.f) monographs about the methods of analysis of a radiopharmaceutical, including specifications;
 - f.g) a radiopharmaceutical manufacturing process flow chart;
 - f.h) a certificate of quality of a radiopharmaceutical, attested by an authorised body;
 - f.i) data on the stability of the radiopharmaceutical;
 - f.j) data on the efficacy and safety of the radiopharmaceutical (in the case of a medicinal radiopharmaceutical product);
 - f.k) data on the safety of a radiopharmaceutical (in the case of a diagnostic radiopharmaceutical product);
- g) for the registration and recording of a biologically active additive (BAA) used to preserve a physiological:
 - g.a) a composition of the BAA;
 - g.b) a method of analysis of the BAA;
 - g.c) a BAA sample - 2 standard packages plus a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;
 - g.d) a certificate of unrestricted sale (if any);
- h) for the registration and recording of a complementary medicinal product:
 - h.a) full composition of the complementary medicinal product;
 - h.b) a method of analysis of the complementary medicinal product;
 - h.c) a complementary medicinal product sample - 2 standard packages plus a quantity sufficient to conduct 2 tests, accompanied by a respective certificate of quality;
 - h.d) monographs about the experience of using complementary medicinal products in medical practice, their efficacy and safety, and respective bibliography materials;
 - h.e) based on the curative principles of complementary medicinal products, substantiation of their effect and designation;
- i) for the registration of contraceptive mechanical devices (except for non-invasive contraceptive mechanical devices):
 - i.a) the name and address of a manufacturer of a contraceptive device;
 - i.b) a standard determining the quality criteria;
 - i.c) 2 samples of a contraceptive device, accompanied with a respective certificate of quality;
- j) for the registration and recording of a dental product:
 - j.a) the name, composition, data on the components and designation of a dental product;
 - j.b) a standard determining the quality criteria;
 - j.c) a certificate of quality of the dental product;
 - j.d) data on the safety of the dental product;
 - j.e) a sample of the dental product;
- k) for the registration and recording of diagnostic products - test systems (according to nosologies), allergens (except for allergens designated for an individual natural person), reagents (for clinical biochemistry and chemistry), and sera:
 - k.a) designation and method of use of diagnostic products (a list with an indication of a manufacturing company's catalogue number and/or a catalogue (if any));
 - k.b) data on the safety and efficacy of a diagnostic product when used *in vivo*;
 - k.c) quality assessment criteria and data on the stability of the diagnostic product (if necessary).

21. Type I variations (of less significant importance):

a) Type IA variations:

a.a) changes in the manufacturing licence - provided that a renewed manufacturing licence is submitted;

a.b) change in the name of a pharmaceutical product:

provided that:

a.b.a) a new name does not cause confusion with an international off-patent name and/or a registered pharmaceutical product name;



a.b.b) if there is a generally recognised name, the change shall be made in favour of a pharmacopoeia name or an international off-patent name;

a.c) change in the name and/or legal address of a trade licence holder - a subject entitled to registration - provided that the manufacturer is not changed;

a.d) change of the manufacturer of an active substance - provided that the specifications and methods of quality control of the substance comply with the universally recognised pharmacopoeia;

a.e) change in the lettering, coating and other marking of tablets, imprints and in the lettering of capsules - provided that a new lettering does not cause confusion with other tablets and capsules;

a.f) change of the labelling of primary packaging, and the labelling and design of secondary packaging - provided that 2 new samples are presented;

a.g) change in the quantity of the pharmaceutical product in a package - provided that the packaging material is not changed;

b) Type IB variations:

b.a) change to an inactive substance - provided that the following is not changed:

b.a.a) similar functional characteristics;

b.a.b) solubility - for solid forms of medicinal products;

b.b) removal of a dye or substitution of one dye with another;

b.c) addition, removal or change of flavouring agents - provided that the following is not changed:

b.c.a) similar functional characteristics;

b.c.b) solubility - for solid forms of medicinal products;

b.d) mass of tablet coating or capsule shell - provided that solubility is not changed;

b.e) a qualitative change in the composition of primary packaging - provided that the proposed packaging material possesses properties equivalent to those of the preceding packaging material; such change shall not apply to sterile products;

b.f) removal of an indication for use or a mode of administration - provided that the safety and quality of the preparation is preserved and confirmed by the retrospective data of a pre-clinical trial;

b.g) minor changes in the manufacturing of an active substance - provided that undesirable changes are not made in the specification of a substance, physical properties of a substance are not changed, a new impurity is not added or an impurity level is not changed, which require conducting a study of finished product safety;

b.h) change in the volume of a batch/lot of an active substance - provided that the analysis of substance control data states that the manufacturing process integrity has not been disturbed and/or physical properties of the substance have not been changed;

b.i) minor changes in the manufacturing of a pharmaceutical product - provided that the specifications of the preparation have not been changed; a new technological process shall ensure the manufacturing of an identical preparation in terms of quality, efficacy and safety;

b.j) change in the volume of a batch of a finished product - provided that the manufacturing process integrity has not been disturbed;

b.k) change in the specifications of a pharmaceutical product - provided that the specifications are improved or complemented with new quality control tests of the preparation, and the limits for the variation of parameters are determined;

b.l) synthesis or restoration of adjuvants that are described in the primary registration documents and are not specified in the pharmacopoeia - provided that the specifications, composition and level of impurities have not been changed, which requires conducting a study of the safety of the finished product; as well as physical and chemical properties of the finished products have not been changed;

b.m) change in the specifications of adjuvants of a pharmaceutical product (except for vaccine adjuvants) provided that the specifications are improved or complemented with new quality control tests of a preparation, and the limits for the variation of parameters are determined;

b.n) extension of the shelf life of a pharmaceutical product specified during the licensing - provided that data on the stability of the preparation are presented, according to a record approved when obtaining a trade licence; the data show that the shelf life has not been reduced; the shelf life does not exceed five years;

b.o) change in the shelf life after the first opening of a package - provided that the analysis of data on the stability of the preparation specifies that the shelf life of the preparation, which was approved according to the specifications presented when obtaining a trade licence, has not been reduced;

b.p) change in the shelf life of the pharmaceutical product after its restoration - provided that the analysis of data on the stability of the preparation specifies that the shelf life of the restored preparation, which was approved according to the specifications, has not been reduced;

b.q) change in the storage conditions - provided that the analysis of data on the stability of a preparation specifies that the shelf life of the preparation, which was approved according to the specifications presented when obtaining a trade licence, has not been reduced. The data on the stability of the preparation, according to the specifications, approved when obtaining a trade licence, shall be



presented;
b.r) change in the method of testing an active substance -
provided that the outcome of the validation (test for reliability) of the method shows that the new method of testing is equivalent to the preceding one;
b.s) change in the method of quality control of the pharmaceutical product -
provided that the specifications of the preparation have not been changed; the outcome of the validation of the method shows that the new method of quality control is equivalent to the preceding one;
b.t) relevant change in the supplement to the pharmacopoeia
provided that the change is made for the purpose of entry into effect of a new supplement of the pharmacopoeia
b.u) change in the method of testing of a non-pharmacopoeia adjuvant -
provided that the outcome of the validation of the method shows that the new method of testing is equivalent to the preceding one;
b.v) change in the method of testing of primary packaging -
provided that the outcome of the validation of the method shows that the new method of testing is equivalent to the preceding one;
b.w) change in the method of testing of an injection device -
provided that the outcome of the validation of the method shows that the new method of testing is equivalent to the preceding one;
b.x) change in the form of the primary packaging -
provided that the quality and stability of the finished product in the package has not been changed; as well as the interaction between the packaging material and the preparation has not been changed;
b.y) change in the size and average weight of tablets, capsules, and suppositories, without a qualitative change in their composition -
provided that solubility has not been changed.

22. Type II variations subject to registration:

a) change in the form, effect and method of administration of the pharmaceutical product:

a.a) change in bioavailability;

a.b) change in pharmacokinetics;

a.c) change in the effect of the pharmaceutical product;

a.d) change in the therapeutic form or addition of a new therapeutic form;

a.e) addition of a new method of administration;

b) changes in active substances:

b.a) addition of one or more active substances, including an antigenic vaccine component;

b.b) removal of one or more active substances, including an antigenic vaccine component;

b.c) change in the quantity of active substances;

b.d) substitution of an active substance with other salt (essential complex) derivative (with components having the same therapeutic properties), with other isomer, isomer mixture or isolated isomer mixture;

b.e) substitution of a biological or biotechnological product with another substance or product having a different molecular structure; modification of a carrier, used to generate an antigenic material;

c) changes in therapeutic indication:

c.a) addition of an indication for use in other therapeutic field (treatment, prevention, diagnostics);

c.b) removal of an indication for use in other therapeutic field (treatment, prevention, diagnostics);

d) change in the place of manufacturing.

23. The amount of the fee for the state registration of a pharmaceutical product through the national regime shall be defined by law.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 3402 of 5 September 2018 – website, 25.9.2018

Article 11¹² - Pharmaceutical product sample

1. A pharmaceutical product sample shall be the means of comparison for performing random control by the Agency with pharmaceutical products available in the distribution network.

2. The Agency shall use a pharmaceutical product sample to visually compare the labelling of a pharmaceutical product and to conduct a laboratory test.

3. The Minister shall define a procedure for replacing pharmaceutical product samples kept by the Agency.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 11¹³ - Exceptional cases of importing pharmaceutical products circumventing the regimes for granting a marketing authorisation in Georgia

A pharmaceutical product may be imported circumventing the regimes for granting marketing authorisation in Georgia, for non-commercial purposes in the following cases:

a) for pre-clinical and clinical trials;

b) for registration - as a sample;

c) for individual needs of a natural person;

d) for an exhibition, symposium, conference, forums, and congress - as a sample, without the right to sell;

e) for re-export;

f) for exposing it to a customs procedure of storage of goods at the customs warehouse/customs terminal and/or of transit;

g) as a bulk pharmaceutical product intended for local manufacturing;



h) under particular circumstances (a natural disaster, mass injury of the population, epidemic, rare disease) for humanitarian purposes, as well as in the case of a special state interest, with the consent of the Ministry.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 3806 of 12 November 2010 - LHG I, No 66, 3.12.2010, Art. 414

Law of Georgia No 4125 of 17 December 2010 - LHG I, No 75, 27.12.2010, Art. 477

Law of Georgia No 5967 of 27 March 2012 - website, 12.4.2012

Chapter V – Manufacturing of Therapeutic Agents

Article 12 - Manufacturing of a pharmaceutical product

1. The manufacturing of a pharmaceutical product shall be subject to a permit regime.

2. In Georgia, the manufacturing of unregistered pharmaceutical products shall be permitted for the purpose of their registration, pre-clinical and clinical trials, and export.

3. The Agency shall issue permits for manufacturing a pharmaceutical product.

4. Georgia shall selectively recognise a list of international, regional and national GMP (Good Manufacturing Practice) standards, and the Government of Georgia shall recognise it.

5. The permit conditions for manufacturing a pharmaceutical product shall be defined by the legislation of Georgia.

6. For the purposes of this Law, an authorised pharmacy that prepares pharmaceutical products according to magistral formula prescription and officinal prescription shall not be considered as the manufacturing of a pharmaceutical product and shall not be subject to a manufacturing permit; the same shall apply to a pharmacy at a healthcare facility that is engaged in packing pharmaceutical products in amounts necessary for use in a healthcare facility.

7. The manufacturer of a batch of a pharmaceutical product shall be responsible for the safety, quality and efficacy of the manufactured pharmaceutical product.

8. The Government of Georgia shall gradually ensure introducing a national manufacturing GMP standard under the principle of risk management.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 13 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Article 14 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 23 of 18 June 2008 - LHG I, No 11, 4.7.2008, Art. 79

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 15 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Chapter VI – Sale of a pharmaceutical product

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 16 - Wholesale and retail sale of a pharmaceutical product

1. Retail sale of a pharmaceutical product shall be carried out by an authorised pharmacy, pharmacy (specialised retail outlet), retail outlet, and in cases determined by the legislation of Georgia - by pharmaceutical personnel or a natural person acting as an entity of independent medical practice.

2. An authorised pharmacy shall be subject to permit control, and may sell pharmaceutical products falling under the first, second, and third groups, as well as prepare pharmaceutical products according to magistral formula prescription or officinal prescription.

3. A pharmacies (specialised retail outlets) may sell pharmaceutical products falling under the second and third groups, and retail outlets - only pharmaceutical products falling under the third group. At the same time, there may be a separate, isolated pharmacy (specialised retail outlet) with a separate entrance, as well as a pharmacy (specialised retail outlet) located in an isolated space within a retail outlet.

4. In order to improve the access of the population to pharmaceutical products, pharmaceutical personnel or an entity of independent medical practice may carry out retail sale of pharmaceutical products (except for pharmaceutical products under special control) in a village and daba (urban-type settlement).

5. The commencement and completion of wholesale and retail sale of a pharmaceutical product shall be subject to mandatory notification of the Agency. The Ministry shall approve a form and a procedure for notifying the Agency.

6. The use by an entity providing healthcare services of a pharmaceutical product under special control, which is a part of provision of healthcare services, shall not be subject to a permit.

7. Permit conditions for the sale by an authorised pharmacy of a pharmaceutical product under special control and the procedure for dispensing such a product shall be defined by the legislation of Georgia.

8. It shall be prohibited to sell a pharmaceutical product at a market and marketplace, as well as in an outdoor retail outlet and portable retail outlet.



9. It shall be prohibited to sell to minors pharmaceutical products falling under the first and second groups under Article 11² of this Law.

10. It shall be prohibited to sell the following pharmaceutical products over the counter:

- a) pharmaceutical products falling under the first group;
- b) pharmaceutical products falling under the second group.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 17 - Requirements for pharmaceutical product sellers

1. The principle of regulating the sale of a pharmaceutical product shall be the provision of conditions for storage and dispensing of a pharmaceutical product and appropriate issuing of documents necessary for registering batches of sold pharmaceutical products.

2. A pharmaceutical product seller shall be obliged to register the batch of the pharmaceutical product intended for sale.

3. A pharmaceutical product seller shall be obliged to introduce modern means of storage of pharmaceutical products and shall store and later sell pharmaceutical products in such conditions that protect the products from the negative impact of environmental factors (temperature, humidity).

4. A pharmaceutical product seller shall be obliged to store a pharmaceutical product in full compliance with sanitary and hygiene/technical conditions provided in the patient information leaflet of the pharmaceutical product.

5. The Ministry shall define, according to this article, the sanitary and hygiene/technical conditions to be complied with by pharmacies (specialised retail outlets) and retail outlets.

6. A retail outlet may sell a pharmaceutical product, if:

a) the pharmaceutical product is positioned with a special inscription in a place specially designated for it, so that it is separated from other products and may be distinctly distinguished;

b) a pharmacy (specialised retail outlet), which is located within a retail outlet, has a separate, isolated space for selling a pharmaceutical product; at the same time, in such pharmacies (specialised retail outlets) a pharmaceutical product is sold by designated medical or pharmaceutical personnel ('the designated personnel') who are prohibited from simultaneously supervising other products and/or performing other work;

c) a pharmaceutical product is protected from adverse environmental impact (including direct sunlight, humidity, temperature, etc.), according to the storage conditions specified in the patient information leaflet;

d) a pharmaceutical product is sold, stored and placed in full compliance with sanitary and hygiene conditions.

7. Pharmaceutical products falling under the second group shall not be accessible for consumers without the designated personnel, while pharmaceutical products falling under the third group shall be accessible for consumers without the designated personnel under the requirements provided for by this Law.

8. Prior to their destruction, expired and spoilt pharmaceutical products shall be stored separately and in isolation from other pharmaceutical products.

9. If a pharmaceutical product seller has a reasonable doubt that a pharmaceutical product does not have marketing authorisation in Georgia, is counterfeit, flawed, spoilt, or expired:

a) the seller shall be obliged to:

a.a) suspend sale of a dubious pharmaceutical product;

a.b) immediately notify the Agency;

b) the Agency shall be obliged to:

b.a) check the information received from the seller;

b.b), notify the seller, if the doubt is not confirmed, within a reasonable period of time;

b.c) supervise the removal of a pharmaceutical product from wholesale and retail networks if a pharmaceutical product batch is found not to have marketing authorisation in Georgia, or to be counterfeit, flawed, spoilt, or expired.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 17¹ - Seizure and destruction of a pharmaceutical product

A pharmaceutical product shall be subject to seizure by the Agency and destruction at the expense of the product owner, according to the procedure approved by the Ministry or under recognised guidelines, if:

a) it does not have marketing authorisation in Georgia, is counterfeit, flawed, spoilt, or expired;

b) it has become known that the pharmaceutical product has been wrongly labelled and/or may pose a threat to a consumer's life or health, due to an unexpected error committed at the manufacturing stage.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Chapter VII – (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 18 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122



Article 18¹ - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Article 18² - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Article 18³ - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Article 18⁴ - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Article 18⁵ - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Article 18⁶ - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 18⁷ - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 3 June 2005 - LHG I, No 29, 21.6.2005, Art. 183

Law of Georgia No 5998 of 21 March 2008 - LHG I, No 9, 4.4.2008, Art. 73

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 19 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 2251 of 8 May 2003 - LHG I, No 13, 2.6.2003, Art. 79

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Chapter VIII – Substances, Agents under Special Control, and Their Medicinal Forms

Article 20 - Substances and agents under special control, and their drug forms

1. In line with the healthcare and public order state policy, narcotic drugs and agents containing narcotic drugs, poisons and agents containing poisons, certain psychotropic and potent substances shall be subject to special state control.

2. The list of substances and agents under special control, and their drug forms shall comply with the requirements of international conventions in the field.

3. The Ministry shall, as necessary, supplement an existing list, taking into consideration the local narcotic drug situation, and the practices of judicial and investigative bodies.

Law of Georgia No 3092 of 5 July 2018 – website, 11.7.2018

Article 21 - Control over the circulation of substances and agents under special control, and their drug forms

1. The manufacturing and legal circulation of substances and agents under special control, and their drug forms shall be regulated under the legislation of Georgia.

2. The Ministry shall define the annual demand for narcotic drugs and respective quotas, including the export/import quota for these substances.

3. Every person engaged in the legal circulation of substances and agents under special control, and their drug forms shall submit the information to the Ministry, according to the established procedure.

Law of Georgia No 2560 of 12 February 2010 - LHG I, No 6, 22.2.2010, Art. 21

Law of Georgia No 3092 of 5 July 2018 – website, 11.7.2018

Article 22 - Circulation of radiopharmaceuticals

The procedures for packaging, storing, importing, transporting, dispensing, administering and destruction of radiopharmaceutical preparations used in medical practice shall be defined by the legislation of Georgia.

Chapter IX – (Deleted)



Article 23 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 24 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Article 25 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Chapter X – Monitoring of Side Effects of Medicines

Article 26 - Monitoring of side effects of medicines

1. General physicians of the medical and preventive treatment network, medical service specialists of healthcare facilities and agencies of the Ministry shall participate in a unified system of side effects monitoring.

2. The unified coordination of the monitoring system and the analysis of the received information shall be performed by the Drug Agency that shall:

a) collect information about side effects of a medicine, analyse and generalise it;

b) exchange this information with healthcare services of other countries and the World Health Organisation;

c) organise the expertise of data obtained and prepare recommendations on releasing and withdrawing from circulation of a medicine, and revoking of a certificate of registration of a medicine;

d) gradually study the incompatibility and interaction of medicines, generalise data on therapeutic agents, and prepare information material.

3. The Ministry shall develop and approve the procedure and sequence of forming an information flow on side effects of medicines from the healthcare network.

4. Subjects of the circulation and use of therapeutic agents shall be obliged to provide the Drug Agency with information on all cases of side effects of a therapeutic agent and other particularities of the interaction of the therapeutic agent, which are not indicated in its patient information leaflet.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 3092 of 5 July 2018 – website, 11.7.2018

Chapter XI – (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 1703 of 24 September 2009 - LHG I, No 29, 12.10.2009, Art. 185

Article 27 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1703 of 24 September 2009 - LHG I, No 29, 12.10.2009, Art. 185

Article 28 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Chapter XII – (Deleted)

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 29 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 30 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 31 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 32 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140



Article 33 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 34 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 36 - (Deleted)

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 377 of 13 August 2004 - LHG I, No 25, 27.8.2004, Art. 122

Article 37 - (Deleted)

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Chapter XII¹ – Responsibility in the Field of Circulation of Pharmaceutical Products

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Article 37¹ - Bases of responsibility regarding the quality and safety of a pharmaceutical product

1. The responsibility of persons engaged in the circulation of a pharmaceutical product shall be classified according to the following bases:

- a) an authorisation holder and the State shall be responsible for the safety, quality and efficacy of a pharmaceutical product that has been granted marketing authorisation in Georgia under the national regime of state registration of a pharmaceutical product;
- b) the State shall be responsible for the safety, quality and efficacy of a pharmaceutical product that has been granted marketing authorisation under the recognition regime of state registration of a pharmaceutical product;
- c) a manufacturer of a pharmaceutical product batch shall be responsible for the compliance with the documents submitted when registering a pharmaceutical product that has been granted marketing authorisation in Georgia under the national regime of state registration of a pharmaceutical product;
- d) if, after placing an imported pharmaceutical product in the distribution network, its property changes, as a result of which it no longer complies with quality and safety standards, the responsibility shall rest with an importer and/or a representative of the respective section of the distribution network; culpability shall be established according to the procedure determined by the legislation of Georgia;
- e) a pharmaceutical product seller shall be responsible for the violation of conditions for the wholesale and retail sale of a pharmaceutical product, which include all the operations related to the procurement, storage, supply and sale of the pharmaceutical product.

2. The responsibility of a person for a violation identified in the course of pharmaceutical activities shall be defined by this Law and according to the legislation of Georgia.

3. The body (official) authorised by the Ministry shall draw up a report of an administrative offence, while a court shall review the case.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 1703 of 24 September 2009 - LHG I, No 29, 12.10.2009, Art. 185

Article 37² - Illegal pharmaceutical activity

1. Performing an activity without a permit for manufacturing a pharmaceutical product, for export or import of a pharmaceutical product under special control, of an authorised pharmacy, and for a clinical trial of a pharmacological product shall be subject to a fine in the amount of GEL 8 000.

2. The same act committed repeatedly shall be subject to a fine in the amount of GEL 16 000.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 37³ - Violation of permit conditions for manufacturing a pharmaceutical product, for export or import of a pharmaceutical product under special control, of an authorised pharmacy, and for a clinical trial of a pharmacological product

The violation of permit conditions for manufacturing a pharmaceutical product, for export or import of a pharmaceutical product under special control, of an authorised pharmacy, for a clinical trial of a pharmacological product shall be subject to a fine in the amount of GEL 2 000.

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 37⁴ - Violation of pharmaceutical activity procedures

1. Preparation and sale of a pharmaceutical product by unauthorised personnel (non-pharmaceutical personnel/an entity not authorised to perform independent medical activity) shall be subject to a fine in the amount of GEL 4 000 and to seizure of the subject in violation of offence.

2. Violation of the procedure for preparing a pharmaceutical product, and violation of storage conditions determined in



- the patient information leaflet shall be subject to a fine in the amount of GEL 2 000 and to seizure of the subject in violation.
3. Violation of the procedure for selling a pharmaceutical product (except for a pharmaceutical product falling under the first group under Article 11² of this Law) shall be subject to a fine in the amount of GEL 500.
4. An act under paragraph 3 of this article, committed repeatedly, shall be subject to a fine in the amount of GEL 1 000.
5. Violation of the procedure for selling (dispensing) a pharmaceutical product falling under the first group under Article 11² of this Law shall be subject to a fine in the amount of GEL 6 000.
6. An act under paragraph 5 of this article, committed repeatedly, shall be subject to a fine in the amount of GEL 12 000.
7. The sale of a substandard, expired, or spoilt pharmaceutical product shall be subject to a fine in the amount of GEL 6 000 and to seizure of the subject in violation.
8. Circulation of a counterfeit pharmaceutical product in the Georgian market shall be subject to a fine in the amount of GEL 20 000 and to seizure of the subject in violation.
9. Violation of the procedures of the entry in the register, manufacturing, standardisation, labelling, dispatching-transporting, importing-exporting, re-exporting, batch registration and destruction of a therapeutic agent product shall be subject to a fine in the amount of GEL 1 600 and to seizure of the subject in violation.
10. An act under paragraph 9 of this article, committed repeatedly, shall be subject to a fine in the amount of GEL 4,000 and to seizure of the subject in violation.
- Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149*
Law of Georgia No 2560 of 12 February 2010 - LHG I, No 6, 22.2.2010, Art. 21
Law of Georgia No 3556 of 21 July 2010 - LHG I, No 46, 4.8.2010, Art. 297
Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 37⁵ - Circulation of a pharmaceutical product circumventing the regimes for granting marketing authorisation to a pharmaceutical product in Georgia and/or circulation of a pharmaceutical product that has not been granted marketing authorisation in Georgia

1. Circulation of a pharmaceutical product circumventing the regimes for granting marketing authorisation to a pharmaceutical product in Georgia and/or circulation of a pharmaceutical product that has not been granted a marketing authorisation in Georgia shall be subject to a fine in the amount of GEL 6 000 and to seizure of the subject in violation.
2. The same act committed repeatedly shall be subject to a fine in the amount of GEL 12 000 and to seizure of the subject in violation.
- Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149*
Law of Georgia No 2560 of 12 February 2010 - LHG I, No 6, 22.2.2010, Art. 21
Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 37⁶ - Violation of procedures for advertising a pharmaceutical product

- Violation of procedures for advertising a pharmaceutical product (with regard to both the customer and the contractor parties) shall be subject to a fine in the amount of GEL 2 000.
- Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149*
Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 37⁷ - Commencement and completion of the sale of a pharmaceutical product without mandatory notification of the Agency

1. According to Article 16(5) of this Law, the commencement and completion of the sale of a pharmaceutical product without mandatory notification of the Agency shall be subject to a fine in the amount of GEL 2 000.
2. The same act committed repeatedly shall be subject to a fine in the amount of GEL 12 000 and to seizure of the subject in violation.
- Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149*
Law of Georgia No 2560 of 12 February 2010 - LHG I, No 6, 22.2.2010, Art. 21
Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 37⁸ - Change in the packaging and labelling of a pharmaceutical product without registration or mandatory notification to the Agency

- A change in the packaging and labelling of a pharmaceutical product without registration or mandatory notification to the Agency shall be subject to a fine in the amount of GEL 2 000 and to suspension of sale until the elimination of the violation.
- Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149*
Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 37⁹ - Selling to minors pharmaceutical products falling under the first and second groups under Article 11² of this Law

- Selling to minors of pharmaceutical products falling under the first and second groups under Article 11² of this Law shall be subject to a fine in the amount of GEL 500.
- Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013*

Article 37¹⁰ - Violation of the conditions established under the technical regulations on the sanitary and



hygienic/technical conditions for pharmacies (specialised trade facilities) and retail trade facilities

1. Violation of the conditions established under the technical regulations on the sanitary and hygienic/technical conditions for pharmacies (specialised trade facilities) and retail trade facilities be subject to a fine of GEL 500.

2. The same action committed repeatedly shall be subject to a fine of GEL 1 000.

Law of Georgia No 3816 of 27 June 2015 - website, 3.7.2015

Chapter XIII – Transitional and Final Provisions

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Article 38 - Transitional and final provisions

1. Article 14(6) of this Law shall be applicable to medicines to be put into retail sale that will be registered or re-registered on the territory of Georgia, according to the established procedure, from 1 January 2003.

2. (Invalid).

2¹. Article 16(9) of this Law shall enter into force on 1 January 2014, while Article 16(10)(b) shall enter into force on 1 September 2014.

2². Article 4¹(2) and (3) of this Law shall only apply to the registration procedures to be performed under the national regime of state registration within the territory of Georgia after entry of this Law into force.

3. Article 11(11) of this Law shall enter into force as from 1 January 2006.

4. Within three months after this Law enters into force, the Ministry of Agriculture of Georgia shall:

a) develop a procedure for state registration, re-registration or revocation of registration and for quality/safety control of preparations (agents) for veterinary use manufactured in and imported into Georgia;

b) approve forms of certificates of registration of preparations for veterinary use.

5. Articles 6, 7 and 8 of this Law shall be declared void as from 15 December 2009.

Law of Georgia No 1191 of 18 December 2001 - LHG I, No 36, 31.12.2001, Art. 140

Corrections - LHG I, No 5, 21.3.2002, p. 11

Law of Georgia No 1356 of 10 April 2002 - LHG I, No 9, 26.4.2002, Art. 43

Law of Georgia No 1848 of 25 December 2002 - LHG I, No 2, 9.1.2003, Art. 5

Law of Georgia No 1918 of 11 October 2005 - LHG I, No 45, 1.11.2005, Art. 310

Law of Georgia No 23 of 18 June 2008 - LHG I, No 11, 4.7.2008, Art. 79

Law of Georgia No 1586 of 10 August 2009 - LHG I, No 26, 27.8.2009, Art. 149

Law of Georgia No 907 of 30 July 2013 - website, 20.8.2013

Law of Georgia No 1862 of 25 December 2013 - website, 28.12.2013

Law of Georgia No 1923 of 23 December 2017 – website, 11.1.2018

President of Georgia

Eduard Shevardnadze

Tbilisi

17 April 1996

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