LAW OF GEORGIA
ON MEDICINES AND PHARMACEUTICAL ACTIVITIES

This Law shall establish 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 shall include the Constitution of Georgia, international agreements and treaties of Georgia, this Law, and other legislative and subordinate normative acts of Georgia.
2. This Law shall aim to facilitate the increase of population's access to safe pharmaceutical products, and, to ensure this, shall establish a legal framework for regulating the circulation of pharmaceutical products and the rights and duties 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 voluntary registration of the 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 1^1 – Definition of terms

1. Generic pharmaceutical product – a therapeutic agent that has the same qualitative and quantitative content of an active substance (substances) and the same pharmaceutical form as a reference product, and the bioequivalence of which in relation to the reference product has been confirmed by a relevant bio penetration testing. An applicant shall not be required to carry out a bio penetration testing if he/she can demonstrate compliance of the generic pharmaceutical product with the appropriate criteria established by the detailed guidelines;
1^1. 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 introduced to the Georgian market for at least the last 10 years, or an innovative (new original) pharmaceutical product having been granted a marketing authorisation in Georgia.
2. Bulk pharmaceutical product – a pharmaceutical product that has passed all stages of the manufacturing and technological process, except for the final packaging stage.
3. Immunobiological preparation – a medicinal product used for immunobiological prevention and therapy (vaccines, sera, test systems, or products containing allergens).
4. Patient information leaflet – information intended for personnel with medical and pharmaceutical education and/or consumers, which is enclosed with a pharmaceutical product.
5. Prescription – a written notice of a physician to a pharmacist regarding the procedures for preparing, dispensing and administering a pharmaceutical product.
6. Pharmaceutical product prepared according to a magistral formula prescription – a pharmaceutical product prepared for a certain patient.
7. Labelling – information presented on a primary and/or secondary packaging.
8. Secondary packaging – a form of packaging in which a pharmaceutical product 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 form of packaging directly in contact with a pharmaceutical product.
11. Radiopharmaceuticals and diagnostic medical products – preparations with ionising radiation features 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 such as instruments, devices, appliances, medical equipment, dressing material, prosthetic and orthopaedic products, etc.
13. Pharmaceutical product (therapeutic agent) – a medicine or a physiologically active substance derived naturally or by synthesis or a combination thereof, the effect of which on a human body is a result of the pharmacological, immunological or metabolic action, and which is allowed for medical use, including a complementary medicinal product, biologically active additive or a paratherapeutic product voluntarily registered under the National Regime of State Registration of Pharmaceutical Products.
13^1. Similar pharmaceutical product – a product of any form and dosage of a medicine containing 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).
13^2. Biological medicinal product – a medicinal product containing a pharmaceutical substance derived or isolated 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 shall belong to them:
c.a) gene therapy medicinal products (anti-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 recombinant nucleic acid or is composed of this acid;
c.a.b) therapeutic, preventive or diagnostic effect 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, prevention or diagnostics of a disease due to the pharmacological, immunological or metabolic action which is a result of the features of cells and tissues contained therein;
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 containing one or several medical devices, or one or several active implantable medical devices 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 that contains nonviable cells and tissues, has a prevailing responsibility, compared to a medical device, over 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, anthroposophical, or 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 proved by objective evidence.
15. Biologically active additives (BAA, or dietary additives) – a substance used to preserve a physiological state, except for a parenteral therapeutic form.
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 the scientific methods.
18. Circulation of a pharmaceutical product – an activity that includes the preparation, manufacturing, standardisation, quality control, packaging, procurement, shipping and forwarding, storage, sale, provision of information on a pharmaceutical product to the population and specialists, advertisement, marketing, export, import, re-export, usage, destruction 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 the requirements established by the legislation of Georgia, under which the circulation of a pharmaceutical product in the Georgian market shall be permitted, according to the current legislation.
21. Wholesale sales (wholesale distribution) of a pharmaceutical product – activities related to the procurement, storage, supply, export, import and re-export of a pharmaceutical product, except for selling it 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.
22^1. Reference retail price – the maximum limited retail sale price of a pharmaceutical product in GEL, including pharmacy's charges.
22^2. Reference wholesale price – the maximum limited wholesale sale price of a pharmaceutical product in GEL, including wholesale charges.
23. Pharmaceutical product safety – a characteristic based on a comparative analysis of the assessment of the efficacy and damage-causing 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 the identity, quantitative composition, purity,

chemical and biological components of a pharmaceutical product with the pharmacopoeia standard.
26. Control of a pharmaceutical market – a combination of physical, organisational and legal measures for ensuring compliance with the established procedures for the circulation of a pharmaceutical product in the market.
27. Departmental registry of pharmaceutical products of Georgia ('the Departmental Registry') – the list of pharmaceutical products that have been granted a marketing authorisation in Georgia, compiled by the Agency.
27[1]. Reference price catalogue – the official list of reference prices for pharmaceutical products in an established format. The reference price catalogue shall be public and shall be posted on the official webpage of the Ministry.
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 appropriate adjuvants that are subject to one or more consecutive technological processes 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 stage following the distribution, and their appropriate registration in an adjacent zone, after passing an administrative procedure for the appropriate 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 incorrectly labelled as to its identity and/or origin.
34. Random control – an administrative action performed by the Agency, the frequency of which and a method applied correspond to the 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 (specification, article, monograph, temporary article in the pharmacopoeia, or technical condition) – a document containing the quality characteristics of a pharmaceutical product and the methods of analysis to define 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, in accordance with the procedure 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 included in the pharmacopoeia, which has one or more precisely standardised properties and which is used to evaluate the device calibration, measurement method or substance quality.
44. Active substance – a substance received from a manufacturer, which has one or more precisely standardised properties and which is used to evaluate the device calibration, measurement method or substance quality.
45. Clinical trial (testing, or investigation) of a pharmaceutical product – the study of an impact of a pharmacological product on a human body to measure the adverse reactions and to evaluate the efficacy and safety levels.
46. Preparation of a pharmaceutical product – preparation of 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.
48[1]. Therapeutic agent equated to a pharmaceutical product subject to special control – a pharmaceutical product not included on the lists of substances subject to special control but the illegal circulation and abuse of which poses a serious threat to the health of the population, aggravates the current situation related to narcotic drugs in the country, and which is included on the list approved by an order of the Minister.
48[2]. Substandard pharmaceutical product – a therapeutic agent, the quality index (indices) of which fails to meet the quality standards and specification requirements viewed and assessed by the Agency during the registration process, and/or the 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 homogeneity product, who is willing to have the pharmaceutical product registered in accordance with 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 – 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 must 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 a certain country, issued by a state body regulating pharmaceutical products in the country concerned or internationally.
53. Voluntary registration – optional registration, which is permitted only for complementary medicinal products, biologically active additives and paratherapeutic products, the registration of which is performed 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, and of a pharmaceutical product registered before 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 country concerned or internationally.
55. Managed Entry Agreement for Pharmaceuticals ('the Managed Entry Agreement') – for ensuring access to an innovative (new unique) pharmaceutical product, a form for purchasing it (covering/paying its cost) under the special conditions, through direct negotiations between the state and the manufacturer or the trade licence holder of this pharmaceutical product, which provides for the reduction of the risks related to the effectiveness and introduction of an innovative (new unique) pharmaceutical product (medication), the improvement of its clinical consequences (outcome) and/or the restriction of its impact on the budget concerned.
Law of Georgia No 1191 of 18 December 2001 – LHG I, No 36, 31.12.2001, Art. 140
Error 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
Law of Georgia No 7075 of 2 September 2020 – website, 7.9.2020
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022
Law of Georgia No 3807 of 30 November 2023 – website, 19.12.2023

Article 2 – State policy in the field of circulation of pharmaceutical products
The state policy in the field of circulation of pharmaceutical products shall mean the insurance of availability of high-quality, safe and efficacious 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
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

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 appropriate state policy.
1^1. The Government of Georgia shall approve the methodology, rules and conditions for the state regulation of prices for relevant pharmaceutical products.
1^2. The Government of Georgia shall, by a legal act, approve the categories of the Managed Entry Agreement and the procedure for its administration. The legal act of the Government of Georgia shall also define the data of the Managed Entry Agreement to be recorded into the monitoring register. Other terms of the Managed Entry Agreement shall become public under the procedure established by the Managed Entry Agreement.
2. The functions of the Ministry shall be to:
a) develop a state policy in the field of circulation of pharmaceutical products;
b) establish the procedure and conditions for checking the authenticity of a marketing authorisation by a state body regulating pharmaceutical products in the country concerned 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 the procedure for and the format of keeping a departmental registry;
d) determine procedures for removing/destroying a pharmaceutical product without a marketing authorisation in Georgia, and of a counterfeit, defective, flawed, and expired pharmaceutical product, or to ensure the recognition of foreign technical regulations;
d^1) define the price for a pharmaceutical product in accordance with the methodology, rules and conditions for the state regulation of prices for relevant pharmaceutical products approved by the Government of Georgia;
d^2) maintain the reference price catalogue and to ensure its publicity;
d^3) approve the forms of an administrative offence report and an electronic fine receipt and the rule for completing and submitting them, and the form of a writ of execution and the rule for writing it out;
e) develop other appropriate legal acts and to issue them within the scope of its authority to ensure the fulfilment of the obligations defined in this Law.

3. The functions of the Agency shall be 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 to 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 subject to special control, and to control the permit conditions;
e) implement measures against counterfeiting of pharmaceutical products;
f) supervise the destruction/removal of a pharmaceutical product from a sales network if necessary under the legislation of Georgia, and to keep a register of pharmaceutical product sellers, and to carry out their random control;
g) issue a document confirming the market authorisation in Georgia of a pharmaceutical product;
g^1) under the Law of Georgia on Enforcement Proceedings, issue a writ of execution on the enforcement of an administrative offence report;
h) perform other functions defined by the legislation of Georgia.
4. Any person involved in the sales of pharmaceutical products shall ensure the availability of information/documents about the circulation of pharmaceutical products, under the procedure and conditions established by the Minister.
5. For the purposes of this Law, the Agency may request a tax secret from a tax authority.
6. The rule for the coordinated cooperation of the Agency and a tax authority may be determined, and issues necessary for the exchange of information and those for the enforcement of this Law may be defined by a joint order of the Minister and Minister of Finance 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
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022
Law of Georgia No 3807 of 30 November 2023 – website, 19.12.2023

Chapter III – Production and Pharmacological Study of Pharmaceutical Products

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 another 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 means that scientific and technical parts of the registration documents submitted for registration of a pharmaceutical product must be confidential and must not be disseminated as 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 4^1 – 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 to use scientific and technical information on a registered pharmaceutical product to make 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 granted a market authorisation in 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 that 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 4^2 – Liability for non-fulfilment of the obligation to observe the confidentiality and exclusivity of information on a pharmaceutical product

The failure to fulfil the obligations provided for by Articles 4 and 4^1 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 – Development of a new pharmaceutical product and funding of a pharmacological study
The development 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 5^1 – 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 healthy 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 is performed on a healthy volunteer.
5. A clinical trial of a pharmacological product intended for use as a progressive therapy medicinal product may be performed if the pharmacological product is manufactured according to any GMP standard recognised by the Government of Georgia in an enterprise that has 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 1^1(48) and (48^1) 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 the state control of pharmaceutical product safety shall be to protect the Georgian market from a counterfeit, defective, flawed, and expired pharmaceutical product that is not safe 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 10^1 – Measures to be carried out by the State to ensure pharmaceutical product safety
The State shall carry out the following measures to ensure pharmaceutical product safety:
a) the granting of a marketing authorisation in Georgia to a pharmaceutical product;
b) the issuance of a permit for manufacturing a pharmaceutical product;
c) the issuance of a permit for a clinical trial of a pharmacological product;
d) the issuance of a permit for an authorised pharmacy;
e) the issuance of a permit for export or import of pharmaceutical products under special control;
f) the insurance of the possibility to perform system control of the registration of a pharmaceutical product batch;
g) the keeping record of pharmaceutical product sellers;
h) the performance of 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 perform the random control of pharmaceutical product sellers based on risk assessment.
2. During the random control, the Agency may check the status of the compliance by pharmaceutical product sellers with the procedures established for traceability of a pharmaceutical product and with storage conditions.
3. Where so provided for by the legislation of Georgia, the Agency may, for random control purposes, purchase 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, or guidelines containing procedures and conditions for conducting random control, including for purchasing 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 11^1 – Control and supervision of a pharmaceutical market

1. In order to carry out random control of a pharmaceutical product on the basis of the risk assessment, the Agency shall apply laboratory control mechanisms and administrative control mechanisms of the distribution chain.
2. Basically, the Agency shall apply the administrative control mechanism of the distribution chain to control and supervise a pharmaceutical product available on the Georgian market.
3. The laboratory control mechanism shall be applied when there is a high risk of counterfeiting or flawing, the criteria of which is approved by the Minister, 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 exceptional cases, the Agency shall enjoy discretionary powers not to consider the formal criteria to identify the risk, and apply the laboratory control mechanism but as frequently as not to exceed 10 percent of the number of inspections conducted within one year.

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

Article 11^2 – Dividing pharmaceutical products into groups for advertising and retail sales purposes

1. For advertising and retail sales purposes, pharmaceutical products shall be divided into the following 3 groups:
a) the first group shall include pharmaceutical products subject to special control, and therapeutic agents equated with pharmaceutical products subject to special control in terms of the legitimate circulation regime (the Minister shall approve the list of therapeutic agents equated with pharmaceutical products subject to special control and the procedure for their legal circulation);
b) the second group shall include pharmaceutical products inappropriate use of which may cause considerable damage to human health and life, and/or which may not be administered according to the patient information leaflet only, without physician's prescription, and which are available on prescription (the Minister shall determine the procedure for issuing 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 physician's prescription, and which are available without prescription.
2. Pharmaceutical products with the same generic name, form and dosage and with different brand names may not fall under more than one group.
3. The Minister shall define the lists of pharmaceutical products falling under the first and third groups specified in paragraph 1 of this article.
4. Pharmaceutical products falling under the third group shall be defined on the basis of the international practice. All other pharmaceutical products that have been granted a 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 11^3 – 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 11^4 – 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.
Law of Georgia No 1586 of 10 August 2009 – LHG I, No 26, 27.8.2009, Art. 149

Article 11^5 – 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 11^6 – 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 11^{10} 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 11^{11} of this Law.
Law of Georgia No 1586 of 10 August 2009 – LHG I, No 26, 27.8.2009, Art. 149

Article 11^{7} – 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.
4^{1}. 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;
f^{1}) a document certifying that the pharmaceutical product has been manufactured according to the GMP standard (it may be submitted as either the original or a copy, or as an electronic document or in another publicly available form, with reference to the source);
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 7 working days, shall place 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 through 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.
9. The Agency shall, temporarily, until the reason for suspending state registration of a pharmaceutical product through the recognition regime is eliminated, suspend the registration of a pharmaceutical product in Georgia on the basis of a recommendation received from the state body regulating foreign or interstate pharmaceutical products. In addition, when state registration of a pharmaceutical product through the recognition regime is suspended, the suspension shall also apply to all the types of packaging and labelling products that are added to the pharmaceutical product.
10. Expiration of the validity period of state registration of a pharmaceutical product through the recognition regime shall bring about a cancellation of a document evidencing the right for granting a marketing authorisation for a pharmaceutical product in Georgia. In addition, the sale of a pharmaceutical product in circulation in the territory of Georgia, and of a different packaging and labelling product added to a pharmaceutical product shall be allowed until the

expiry of the shelf life.
11. If the validity period for granting a marketing authorisation in Georgia for a pharmaceutical product registered through the recognition regime of state registration of a pharmaceutical product expires, the cancellation of registration of the pharmaceutical product shall apply to a pharmaceutical product with all the types of packaging and labelling that have a marketing authorisation in Georgia.
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
Law of Georgia No 7075 of 2 September 2020 – website, 7.9.2020
Law of Georgia No 1394 of 17 February 2022 – website, 23.2.2022
Law of Georgia No 1453 of 17 March 2022 – website, 24.3.2022

Article 11^8 – 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, within 5 working days after receipt of notification, enter into the Departmental Registry the information on a pharmaceutical product that has been granted marketing authorisation in Georgia but is differently packaged and labelled.
Law of Georgia No 1586 of 10 August 2009 – LHG I, No 26, 27.8.2009, Art. 149
Law of Georgia No 7075 of 2 September 2020 – website, 7.9.2020
Law of Georgia No 1453 of 17 March 2022 – website, 24.3.2022

Article 11^9 – 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 11^{10} – 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 marketing authorisation of a pharmaceutical product in Georgia, and shall remove it from the Departmental Registry.
Law of Georgia No 1586 of 10 August 2009 – LHG I, No 26, 27.8.2009, Art. 149

Article 11^{11} – 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 or English language 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 an inaccuracy identified at the administrative, or scientific and technical review level, an interested person shall be allowed an additional period of up to two months. In addition, the Agency may, only once, inform the interested person about the inaccuracy identified at the administrative, or scientific and technical review level. The elimination of an inaccuracy shall mean presentation of the reasoned data/explanations/materials with regard to all the inaccuracies identified. If an inaccuracy is identified again in the documentation/materials presented additionally, the Agency shall, only once, inform the interested person again in writing. If the inaccuracy is not completely eliminated under the established procedure within the aforementioned period, the Agency shall make the decision to refuse the registration of a pharmaceutical product through the national regime of state registration/the re-registration/registration and recording of a pharmaceutical product, the registration of a Type-II variation or a Type-I variation;
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 make the decision to register or refuse to register a pharmaceutical product or a variation within 3 months in the case of the primary registration of a pharmaceutical product or the registration of a Type-II variation, within 2 months – in the case of the re-registration or the registration and recording of a pharmaceutical product, within 20 calendar days – in the case of registration of a Type-I A variation, and within 40 calendar days – in the case of registration of a Type-I B variation, which shall be documented as an administrative act.

10. If the Agency refuses to register a pharmaceutical product, it shall 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 the 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) if there is a need to issue a new document certifying marketing authorisation.
15. Expiry of the registration validity period shall entail revoking a document certifying marketing authorisation in Georgia.
15^1. If the validity period for a marketing authorisation in Georgia of a pharmaceutical product registered through the national regime of state registration of a pharmaceutical product is expired and/or the marketing authorisation is cancelled, the cancellation of the registration of a pharmaceutical product shall apply to this product with all the types of packaging and labelling that have a marketing authorisation in Georgia. In addition, if the registration of a pharmaceutical product through the national regime of state registration is suspended, the suspension shall also apply to all the types of packaging and labelling that are added to the pharmaceutical product.
16. Circulation of a pharmaceutical product in the territory of Georgia shall be permissible during 5 years after its registration, and after expiry of the registration validity period – until expiry of the shelf life of the pharmaceutical product, and of the different packaging and labelling that are added to 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.
17^1. In the case of making a change in the labelling of primary packaging, and in the labelling and design of secondary packaging as provided for by paragraph 21(a.f) of this article, pharmaceutical products may be imported and they may be produced in Georgia with the packaging and labelling permitted before the change was made, during 12 months after the change is made (transition period). In each following case of making a change in the labelling of primary packaging, and in the labelling and design of secondary packaging, the pharmaceutical products with the labelling of primary packaging, and the labelling and design of secondary packaging that are relevant to that change and that were permitted before the change was made may be allowed on the market.
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;
d^1) a document certifying that the pharmaceutical product has been manufactured according to the GMP standard (it may be submitted as either the original or a copy, or as an electronic document or in another publicly available form, with reference to the source). It must be submitted in compliance with the stages and other conditions defined by the Government of Georgia for submitting the aforementioned document;
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 product, 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, and in other countries as well (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 paratherpautic 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, and in other countries as well (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 complys 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
Law of Georgia No 7075 of 2 September 2020 – website, 7.9.2020
Law of Georgia No 1394 of 17 February 2022 – website, 23.2.2022
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

Article 11^{12} – 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 11^{13} – 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 pharmaceutical products
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 pharmacy (a specialised retail outlet) 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 (a 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 (rural 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 11^2 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.
11. Wholesale sales and/or retail sales of pharmaceutical products (except for the transactions relating to import, export and/or re-export) at prices higher than their reference prices shall be prohibited.
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
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

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 (a specialised retail outlet), which is located within a retail outlet, has a separate, isolated space for selling a pharmaceutical product; at the same time, a pharmaceutical product is sold in such pharmacies (specialised retail outlets) 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 17^1 – Seizure and destruction of pharmaceutical products
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
Law of Georgia No 1586 of 10 August 2009 – LHG I, No 26, 27.8.2009, Art. 149

Article 18^1 – (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 18^2 – (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 18^3 – (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 18^4 – (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 18^5 – (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 18^6 – (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 18^7 – (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 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)
Law of Georgia No 1586 of 10 August 2009 – LHG I, No 26, 27.8.2009, Art. 149

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 overall coordination of the monitoring system of the side effects of a medicine and the analysis of the information materials received shall be performed by the Agency, which:
a) collects information about the undesirable action of a medicine, analyses and generalises it;
b) exchanges the information provided for in subparagraph a) of this paragraph with foreign medical services and the World Health Organisation;
c) organises the expertise of data obtained and prepares recommendations on releasing and withdrawing from circulation of a medicine, and revoking of a certificate of registration of a medicine;
d) studies step-by-step the incompatibility and interaction of medicines, generalises the data on therapeutic agents, and prepares the 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 circulation and use of the therapeutic agents shall provide the Agency with information on all cases of the side effects of a therapeutic agent and other particularities of the interaction of a therapeutic agent, which are not specified 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
Law of Georgia No 7075 of 2 September 2020 – website, 7.9.2020

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 XII[1] – 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 37[1] – Grounds for the responsibility related to the regulation of circulation of pharmaceutical products

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. An administrative offence report provided for by this Law (except for the administrative offences provided for by Articles 37^{11} and 37^{12} of this Law) shall be drawn up by the Agency, while the administrative offence case shall be considered by a court.
4. Administrative offence reports provided for by Article 37^{11} of this Law shall be drawn up by the duly authorised persons of the Agency and the legal entity under public law under the governance of the Ministry of Finance of Georgia – the Revenue Service ('the Revenue Service'), who will review the administrative offence cases at the scene and will impose an administrative sanction on the offender at the very scene. For this purpose, the Agency and the Revenue Service shall ensure the exchange of information, and the planning and implementation of joint actions, when necessary.
5. Administrative offence reports provided for by Articles 37^{11}(3)–(5) and 37^{12} of this Law shall be drawn up by a duly authorised person of the Agency, who will review the administrative offence cases at the scene and will impose an administrative sanction on the offender at the very scene (when an administrative offence provided for by Article 37^{12} of this Law is committed, an administrative sanction may be imposed on the offender electronically, in the case defined, and under the procedure determined by an order of the Minister).
6. When an administrative offence provided for by Article 37^{11} and 37^{12} of this Law is committed, individual administrative acts adopted by the Agency/the Revenue Service with respect to the imposition of a fine as a sanction shall be referred for immediate enforcement and the appeal shall not suspend their enforcement.
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
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

Article 37^{2} – 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 37^{3} – 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 37^{4} – 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 11^{2} 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 11^{2} 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 37^5 – 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 37^6 – 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 37^7 – Commencement and completion of the sale of a pharmaceutical product without mandatory notification of the Agency
1. The commencement and completion of the sale of a pharmaceutical product according to Article 16(5) of this Law, without mandatory notification of the Agency, –
shall carry a fine in the amount of GEL 4 000.
2. The same act committed repeatedly, –
shall carry a fine in the amount of GEL 8 000.
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
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

Article 37^8 – 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 37^9 – Selling to minors pharmaceutical products falling under the first and second groups under Article 11^2 of this Law
Selling to minors of pharmaceutical products falling under the first and second groups under Article 11^2 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 37^{10} – 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

Article 37^{11} – Failure to comply with the reference prices defined for pharmaceutical products
1. Violation of the rule for selling a pharmaceutical product at a price higher than the reference retail price, –
shall carry a warning.
2. The act provided for by paragraph 1 of this article committed repeatedly, –
shall carry a fine in the amount of GEL 5 000.
3. Violation of the rule for selling a pharmaceutical product at a price higher than the reference wholesale price, –
shall carry a warning.
4. The act provided for by paragraph 3 of this article committed repeatedly, –

shall carry a fine in the amount of GEL 15 000.
5. The third and every subsequent commission of the act provided for by paragraph 3 of this article, –
shall carry a fine in the amount of GEL 30 000.
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

Article 37^{12} – Violation of the rule for the availability of information/documents about the circulation of pharmaceutical products
1. Violation of the rule for the availability of information/a document about the circulation of a pharmaceutical product provided for by Article 3(4) of this Law, –
shall carry a warning.
2. The same act committed repeatedly, –
shall carry a fine in the amount of GEL 5 000.
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

Article 37^{13} – Manufacturing of pharmaceutical products without holding a Georgian National GMP (Good Manufacturing Practice) Certificate and wholesale distribution of pharmaceutical products without holding a Georgian National GDP (Good Distribution Practice) Certificate
1. Manufacturing of pharmaceutical products without holding a Georgian National GMP (Good Manufacturing Practice) Certificate, under the conditions provided for by the legislation of Georgia, –
shall carry a fine in the amount of GEL 50 000, with the confiscation of the object of offence.
2. The same act committed repeatedly, –
shall carry a fine in the amount of GEL 100 000, with the confiscation of the object of offence.
3. Wholesale distribution of pharmaceutical products without holding a Georgian National GDP (Good Distribution Practice) Certificate, under the conditions provided for by the legislation of Georgia, –
shall carry a fine in the amount of GEL 30 000, with the confiscation of the object of offence.
4. The same act committed repeatedly, –
shall carry a fine in the amount of GEL 60 000, with the confiscation of the object of offence.
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

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).
2^{1}. 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.
2^{2}. Article 4^{1}(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.
2^{3}. The Government of Georgia shall, before 1 March 2022, by an ordinance, define the stages and other conditions for submitting a document certifying that a pharmaceutical product that has been granted or is intended for granting a marketing authorisation in Georgia under the national or recognition regime of state registration has been manufactured according to the GMP standard.
2^{4}. The Government of Georgia shall, not later than 1 January 2023, ensure the approval of the methodology, the rule and conditions for the state regulation of prices for relevant pharmaceutical products.
2^{5}. The Ministry shall, not later than 15 January 2023, ensure the implementation of actions necessary for introducing the process of state regulation of prices for relevant pharmaceutical products.
2^{6}. Commission of an administrative offence provided for by Articles 37^{11} and 37^{12} of this Law before 15 March 2023 (transition period) shall entail liability of an offender only in the form of a warning.
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 from 15 December 2009.
Law of Georgia No 1191 of 18 December 2001 – LHG I, No 36, 31.12.2001, Art. 140
Error 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
Law of Georgia No 1394 of 17 February 2022 – website, 23.2.2022
Law of Georgia No 2273 of 1 December 2022 – website, 13.12.2022

President of Georgia **Eduard Shevardnadze**

Tbilisi
17 April 1996
No 659–II ს