

Law of Georgia on Drugs and Pharmaceutical Activity

This Law creates legal basis for state provision of lawful practice regarding circulation of pharmaceutical products (*10.08.2009 #1586 be effective from October 15, 2009*)

Chapter I. General Provisions

Article 1. The regulation subject of the Law and its scope of use (*10.08.2009 #1586 be effective from October 15, 2009*)

1. Legislation of Georgia on drugs and pharmaceutical activity includes the Constitution of Georgia, International contracts and agreements of Georgia, this Law and other legislative acts and by-laws of Georgia.
2. The purpose of this Law is to promote the growth of population's access to reliable pharmaceutical products for which the Law establishes legal framework governing circulation of pharmaceutical products and the rights and obligations of individuals and legal entities in this field.
3. State regulation mechanisms specified under this Law shall be applied to the complementary medicinal agent, biologically active supplement and paratherapeutical agent if a person concerned on his/her own initiative carries out their voluntary registration in accordance with the national mode of state registration of pharmaceutical product.
4. Noninvasive contraceptive mechanical agent shall be exempted from the state regulation, specified under this Law

Article 1¹. Definition of terms (*10.08.2009 #1586 be effective from October 15, 2009*)

1. Generic pharmaceutical product – International unpatented reproduced pharmaceutical product.
2. Bulk pharmaceutical product – pharmaceutical product, which passed all manufacturing stages except for final packing.
3. Immunobiological drug – medicinal agent used for immunobiological prophylaxis and therapy (vaccines, serums, test systems).
4. Instruction – Information accompanied to pharmaceutical product and designed for personnel with medical and pharmaceutical education and/or user.
5. Prescription – Written application of a doctor to a pharmacist about rules of preparation, dispensing and administration of pharmaceutical product.
6. Pharmaceutical product prepared by magistral prescription – pharmaceutical product prepared for particular patient.
7. Marking – information, represented on original and/or secondary packing.
8. Secondary packing – the form of packing in which a pharmaceutical product with its original packing is placed.
9. Pharmaceutical product prepared by officinal prescription – pharmaceutical product, prepared in drugstore in accordance with the pharmacopeia.

10. Original packing – the form of packing, which is in direct contact with pharmaceutical product .
11. Radioactive and diagnostic medicinal agent – ionizing and/or chemical agent used in medical practice.
12. Medical-purpose goods– medical goods, used in medical practice for disease prevention, treatment, diagnosis and patient care: tools, equipment, devices, medical apparatus, bandaging material, prosthetics and orthopedic items etc.
13. Pharmaceutical product (medicinal agent) –drug or physiologically active, natural or synthesized substance or their combination, permitted for medical application including complementary medicinal agent, biologically active supplement and paratherapeutical agent, registered voluntarily in accordance with the national mode of state registration of pharmaceutical product.
14. Complementary (homeopathic, anthroposophical, homotoxic) medicinal agent – an agent made from natural origin (mineral, herbal or animal) substance or the combination of substances the action and normality of which is not proved by justified evidences.
15. Biologically active supplement (BAD) – agent for maintenance of physiological state.
16. Paramedicinal agent –mineral, herbal or animal origin agent with certain therapeutic effect containing specific substance of a drug in such form and amount that may be considered as a drug form.
17. Effectiveness of a pharmaceutical product – level of positive influence of a pharmaceutical product on pathological process, established by scientific methods.
18. Circulation of pharmaceutical product – activity which includes preparation, production, standardization, quality control, packing, purchasing, shipping and transportation, storing of pharmaceutical product, delivering of information about it to population and specialists, its advertisement, marketing, export, import, re-export, usage, destruction and other activities, relating to the pharmaceutical product.
19. Raw material – raw materials of any origin, used for preparation of drug directly or after its processing.
20. Authorization of pharmaceutical product for Georgian market– the procedure for establishment of conformity of pharmaceutical product with the requirements specified under the Georgian legislation, on the basis of which circulation of pharmaceutical product in Georgian market is permitted in accordance with the existing legislation.
21. Wholesale trade (wholesale distribution) of pharmaceutical product – transactions relating to the purchase, storage, supply, export, import and re-export of a pharmaceutical product except for its direct sale to the customer.
22. Traceability – Possibility to establish origin of pharmaceutical product and/or its ingredients at production and distribution stages.
23. Safety of pharmaceutical product – characteristic obtained based on comparative analysis of effectiveness and harm-causing risk evaluation of pharmaceutical product.
24. Agency – competent service under control of the Ministry of Labor, Health and Social Affairs of Georgia.

25. Quality of pharmaceutical product – index of conformity of identity, quantitative composition, purity, chemical and biological components to the pharmacopeia standard.
26. Control of pharmaceutical market – set of physical, organizational and legal measures for the provision of conformity to the regulations established regarding circulation of pharmaceutical product in the market.
27. Official register of pharmaceutical products of Georgia (hereinafter referred to as the Register) – list of pharmaceutical products authorized for Georgian market, which is maintained by the Agency.
28. Minister – Minister of Labor, Health and Social Affairs of Georgia.
29. Ministry – Ministry of Labor, Health and Social Affairs of Georgia.
30. Batch – specified amount of initial substance and relevant adjuvant agents subjected to processing in one or more further technological process in such a way to obtain their homogeneity.
31. Batch registration– obligatory indication of the batch number and amount of sale-purchase object in documents certifying transactions made in each interim link following distribution after relevant administrative procedure of registration of pharmaceutical product in Revenue Service, a legal entity of public law of the Ministry of Finance of Georgia and its corresponding registration in adjacent zone.
32. Trade license holder – holder of pharmaceutical product which produces pharmaceutical products itself or makes an order for its production.
33. Adulterated pharmaceutical product – pharmaceutical product deliberately mislabeled with respect to identity and/or its origin.
34. Random inspection–administrative action made by the Agency, the frequency and used method of which correspond to the evaluation of violation risk.
35. Pharmaceutical agent– substance or combination of substances with established pharmacological activity and safety, which is the subject of clinical trial.
36. Preclinical trial of pharmaceutical agent – pharmacological, toxicological and other scientific non-human study of a pharmaceutical agent for the purpose of determination of its specific activity and impact level on physiological system.
37. Pharmacopeia – Set of standards and provisions, specifying quality of pharmaceutical product.
38. Pharmacopoeial standard (specification, item, monograph, temporary pharmacopoeial monograph, standard specification) –the document, describing qualitative characteristics of pharmaceutical product and methods of their analysis, which is the basis for quality evaluation.
39. Distributor of pharmaceutical product – wholesale or retail distributor of pharmaceutical product.
40. Pharmaceutical – metered, finished pharmaceutical product (including, pill, tablet, capsule, ampoule, suppository, caplet etc.).

41. Pharmaceutical activity – activity of natural persons and legal entities involved in the field of pharmaceutical product circulation in accordance with the regulations established under the Georgian legislation.
42. Pharmaceutical substance – substance of any origin, with relevant quality and pharmacological activity used for preparation and/or manufacturing of pharmaceutical product.
43. Reference standard – agent or substance indicated in pharmacopeia, with one or more exactly specified properties, used for evaluation of instrument calibration, measurement method or quality of substance.
44. Active substance – agent or substance received from the manufacturer, with one or more exactly specified properties, used for evaluation of instrument calibration, measurement method or quality of substance.
45. Clinical trial (examination, study) of pharmaceutical product – study of impact of pharmaceutical agent on human organism for the purpose of determination of side effects, evaluation of effectiveness and safety level.
46. Preparation of pharmaceutical product – preparation of pharmaceutical product in authorized drugstore in accordance with the magistral or officinal prescription.
47. Manufacturing of pharmaceutical product – serial production of pharmaceutical product in enterprise in strict compliance with the requirements of relevant standard.
48. Pharmaceutical product under special control – narcotic drug, psychotropic agent and/or precursor permitted under the Georgian legislation.
- 48¹ Medicinal agent equated to the pharmaceutical product under special control – pharmaceutical product not included into the list of pharmaceutical products under special control but illegal circulation and abuse of which creates threat to public health, aggravates narcological situation existing in the country and is included in the list approved by the order of the Minister.
- 48² Substandard pharmaceutical product – medicinal agent, qualitative indicator(s) of which does not correspond to the quality standards and specification requirements, examined and evaluated by the Agency during registration process, and/or to the international standards
49. Person concerned – manufacturer, trade license holder or any other natural person or legal entity interested in authorization of pharmaceutical product for market, willing registration of pharmaceutical product in accordance with the recognition or national mode of state registration of pharmaceutical product.
50. Recognition of standards and guidelines of preclinical and clinical trials of pharmaceutical agent – approval of international standards, technical regulations and guidelines for application by the Ministry on the basis of Georgian legislation, including international treaties and agreements, in accordance with which preclinical and clinical trials of pharmaceutical agent shall be conducted in Georgia.

51. Quality certificate of pharmaceutical product – document, certifying correspondence of pharmaceutical product with pharmacopeia standards.
52. Certificate of pharmaceutical product (CPP) – document, issued by the relevant country's or intergovernmental regulatory state agency of pharmaceutical products, certifying the right of a pharmaceutical product to be introduced in its own market.
53. Voluntary registration –non-obligatory registration, permitted only for complementary therapeutic agent, biologically active supplement and paratherapeutic agent, registration of which is made by the Person concerned on its own initiative.
54. Introduction of pharmaceutical product authorized for Georgian market with different packaging and marking for the first time - introduction on Georgian market of pharmaceutical product with original and/or secondary packaging and marking other than the packaging and marking of pharmaceutical product authorized by recognition or national mode of state registration, as well as those registered before October 15, 2009, which are authorized for the market under its control, by other country's or intergovernmental regulatory state agency of pharmaceutical products, specified by the Georgian government

Article 2. State policy for pharmaceutical product circulation (*10.08.2009 #1586 be effective from October 15, 2009*)

State policy for pharmaceutical product circulation shall envisage availability of effective, safe and high-quality pharmaceutical product in Georgian market.

Article 3. Role of the state in the field of circulation of pharmaceutical product (*10.08.2009 #1586 be effective from October 15, 2009*)

1. Executive authorities shall provide implementation of Georgian legislation and relevant state policy in the field of circulation of pharmaceutical product.
2. The following shall be the functions of the Ministry:
 - a) Development of state policy in the field of circulation of pharmaceutical product;
 - b) Establishment of regulations and conditions for verification of validity of authorization by other country's or intergovernmental regulatory state agency of pharmaceutical products of pharmaceutical product authorized by recognition or national mode of state registration of a pharmaceutical product for Georgian market, for markets under their control.
 - c) Approval of regulations and format for maintaining of the official register;
 - d) Establishment of rules for withdrawal /disposal of pharmaceutical product without market authorization, as well as adulterated, rejected, unfitted, expired pharmaceutical product, or provision of recognition of technical regulations of other country;
 - e) Development of other relevant legislative acts for the purpose of provision of fulfillment of obligations specified under this Law, and their publication within the scope of its own competence

3. The following shall be the functions of the Agency:
 - a) Authorization of pharmaceutical product for the Georgian market;
 - b) Random inspection of a pharmaceutical product;
 - c) Maintaining of Official register and provision of its publicity;
 - d) Granting of permissions for pharmaceutical production (except for the narcotic drug), clinical trial of pharmaceutical agent, authorized drugstore, export or import of pharmaceutical product subjected to special control, and monitoring of permission conditions;
 - e) Carrying out of measures directed against adulteration of pharmaceutical product;
 - f) In special cases, specified under the Georgian legislation, monitoring of withdrawal of pharmaceutical product from marketing network or its disposal, maintaining of register of pharmaceutical product distributors and their random inspection;
 - g) Issuance of document certifying authorization for the Georgian market;
 - h) Fulfillment of other functions, specified under the Georgian legislation.

Chapter III. Development of pharmaceutical product and pharmacological study

(10.08.2009 #1586 be effective from October 15, 2009)

Article 4. Obligation of keeping of confidentiality and exclusivity of information about pharmaceutical product *(10.08.2009 #1586 be effective from October 15, 2009)*

1. The Agency or other body, carrying out administrative procedures shall be obliged to keep confidentiality regarding information, delivered by the Person concerned, which on the basis of the Georgian legislation is considered as a trade secret.
2. The Agency shall be obliged to keep exclusivity regarding information about pharmaceutical product, which means that:
 - a) the scientific-technical part of registration documentation submitted for the registration of pharmaceutical product shall be confidential and shall not be distributed as the public information;
 - b) any use of scientific-technical information about already registered pharmaceutical product for the purpose of making of decision relating to the registration of similar pharmaceutical product shall not be permitted.
3. Copyright and patent right of the pharmaceutical product manufacturer is protected under Georgian legislation.
4. Non-fulfillment by the Agency of obligations specified under this Article shall involve responsibility in accordance with the Georgian legislation.

Article 5. Development of new pharmaceutical product and financing of pharmacological study

(10.08.2009 #1586 be effective from October 15, 2009)

Development of new pharmaceutical product and financing of pharmacological study shall be free.

Article 6. Repealed from December 15, 2009

Article 7. Repealed from December 15, 2009

Article 8. Repealed from December 15, 2009

Chapter IV. State control of the pharmaceutical product safety

(10.08.2009 #1586 be effective from October 15, 2009)

Article 9. The objective of state control of the pharmaceutical product safety

The objective of state control of the pharmaceutical product safety shall be the protection of Georgian market against adulterated, rejected, unfitted, expired pharmaceutical product without authorization for Georgian market, involving threat to the customers.

Article 10. Repealed (*13.08.2004 #377*)

Article 10¹. Measures to be taken by the state for the provision of pharmaceutical product safety (*10.08.2009 #1586 be effective from October 15, 2009*)

For the provision of pharmaceutical product safety the State shall take the following measures:

- a) Authorization of pharmaceutical product for the Georgian market;
- b) Granting of permission for pharmaceutical production;
- c) Granting of permission for clinical trial of pharmaceutical agent;
- d) Granting of permission for authorized drugstore;
- e) Granting of export or import permission for pharmaceutical product under special control;
- f) Provision of possibilities for system monitoring of registration of pharmaceutical product batch;
- g) Registration of pharmaceutical product distributors;
- h) Random inspection of pharmaceutical product distributors.

Article 11. Random inspection (*10.08.2009 #1586 be effective from October 15, 2009*)

1. The Agency shall be obliged to conduct random inspection of pharmaceutical product distributors based on risk evaluations.
2. During random inspection the Agency shall be entitled to inspect the state of observation of rules established for pharmaceutical product traceability and storage conditions.
3. In cases, specified under the Georgian legislation, the Agency shall be entitled to purchase pharmaceutical product from pharmaceutical product distributors for the purpose of conduction of further random inspection.
4. The Agency shall approve the manual for random inspection (technical regulations, guidelines in which the rules and conditions for conduction of random inspection, including sample purchasing are represented), based on risk evaluation or provide its recognition.

Article 11¹. Market control and monitoring (*10.08.2009 #1586 be effective from October 15, 2009*)

1. For random inspection of pharmaceutical product based on risk evaluation the Agency shall use the laboratory inspection and distribution chain administrative control mechanisms.
2. For the purpose of control and monitoring of pharmaceutical products in Georgian market the Agency shall mainly use the distribution chain administrative control mechanism.
3. Laboratory inspection mechanism shall be used in case of high risk of adulteration or unfitness of pharmaceutical product authorized in accordance with the recognition or national mode of state registration of pharmaceutical product, the criteria of which shall be approved by the Minister.
4. In exceptional cases the Agency shall have discretionary power to not consider formal criteria for risk determination and use laboratory inspection mechanisms but during a year the frequency of inspection shall not exceed 10%

Article 11². Division of pharmaceutical product into groups for the purpose of advertisement and retail sale (10.08.2009 #1586 be effective from October 15, 2009)

1. For the purpose advertisement and retail sale pharmaceutical product shall be divided into three groups:
 - a) First group includes pharmaceutical product under special control, as well as medical agent equated to it in terms of legal circulation mode (the list of therapeutic agents equated to a pharmaceutical product under special control, as well as the regulations for their legal circulation shall be specified by the Minister);
 - b) Second group includes pharmaceutical product, undue administration of which may be detrimental to human health and life and/or administration of which is not allowed only in accordance with the instruction, without doctor's order, and which is put on prescription (rules for writing of prescription for pharmaceutical product included into second group shall be specified by the Minister);
 - c) Third group includes pharmaceutical product, administration of which in accordance with the instruction is permitted without doctor's order, and which is put without prescription.
2. It shall not be allowed to include pharmaceutical product with the same generic name, form and dosage, different trade name into more than one group.
3. The list of pharmaceutical products, included into first and third groups under this Article shall be specified by the Minister.
4. Pharmaceutical product, included into third group shall be specified on the basis of international practice. All other pharmaceutical products authorized for Georgian market shall be automatically included into the second group.

Article 11³. Advertisement of pharmaceutical product (10.08.2009 #1586 be effective from October 15, 2009)

1. Advertisement of pharmaceutical product shall mean the material distributed through mass media, as well as in any form and means and/or acts the purpose of which is the promotion of pharmaceutical product usage.
2. Advertisement of pharmaceutical product under special control (included into first group), included into second group and a pharmaceutical product without authorization for Georgian market shall not be allowed.
3. Advertisement of pharmaceutical product of third group shall be allowed on the basis of previous agreement of advertisement text with the Agency and with fulfillment of the following conditions:
 - a) If an advertisement of pharmaceutical product is distributed as a printed material, it shall include warning indication: "Prior to administration, please read the instruction; for detailed information about side effects, contact your doctor";
 - b) If an advertisement of pharmaceutical product is distributed not as printed material, the warning indication shall be audible;
 - c) If an advertisement of pharmaceutical product is distributed via TV, and it is perceived visually, as well as audibly, the warning indication shall be visible (readable) during no less than three seconds and it shall be audible as well.
4. Agreement of advertisement text with the Agency means the agreement that the advertisement text is in conformity with the information indicated in instruction.
5. It shall not be allowed that the advertisement text content of pharmaceutical product be different from the indications given in user instruction.
6. It shall not be allowed to indicate disease in the advertisement text of complementary therapeutic agent, biologically active supplement and paratherapeutic agent that are not registered as a pharmaceutical product, as well as not registered voluntarily under national mode of state registration of pharmaceutical product, and their representation as a pharmaceutical product.
7. Advertisement of pharmaceutical product, voluntarily registered under national mode of state registration of pharmaceutical product is exempted and the regulation referred to in this Article shall not be applied, except for subparagraph 5 thereof.
8. The Agency shall carry out monitoring of pharmaceutical product advertisement with the provision of fulfillment of conditions, established under this Law.
9. The following shall not be considered as an advertisement:
 - a) Marking, instruction of pharmaceutical product;
 - b) Business correspondence;
 - c) Booklet and reference materials of factual or informational nature if the information contained refers only to the changes of pharmaceutical product and/or safety measures;

- d) Information relating to health and/or disease if it directly or indirectly does not contain any reference to treatment by a pharmaceutical product;
 - e) Delivery of information about pharmaceutical product to healthcare practitioners and pharmacists.
10. Distribution of first and second group pharmaceutical products, as well as pharmaceutical products without market authorization for Georgian market to the population shall not be allowed.

Article 11⁴. Modes of Authorization of pharmaceutical product for Georgian market

1. Authorization of pharmaceutical product for Georgian market shall be carried out in accordance with the following modes:
 - a) Recognition mode of state registration of pharmaceutical product;
 - b) National mode of state registration of pharmaceutical product .
2. The basis for application of recognition mode of state registration of pharmaceutical product shall be the differentiation of other country's or intergovernmental regulatory state agency of pharmaceutical products according to reliability, authorization of only high-quality pharmaceutical products for their own markets.
3. Requirements of safety, effectiveness and quality specified by other country's or intergovernmental regulatory state agency of pharmaceutical products regarding authorization of pharmaceutical products for markets under its control shall be unilaterally acknowledged by Georgia and repeated examination for the establishment of conformity of the safety, quality and therapeutical effectiveness of pharmaceutical product with the same or similar requirements shall not be conducted.

Article 11⁵. Term of authorization of pharmaceutical product for Georgian market (*10.08.2009 #1586 be effective from October 15, 2009*)

1. The term of authorization of pharmaceutical product for Georgian market shall be established in accordance with the recognition and national modes of state registration of pharmaceutical product.
2. After expiration of the term of authorization of pharmaceutical product for Georgian market, circulation of pharmaceutical product except for its import shall be permitted up to the expiration of shelf life of pharmaceutical product already in circulation at the territory of Georgia.

Article 11⁶. Official register (*10.08.2009 #1586 be effective from October 15, 2009*)

1. Including of pharmaceutical product into official register shall mean its authorization for Georgian market.
2. Registration number of a pharmaceutical product, a person concerned, manufacturing country, trade name, international unpatented name (if any), form, dosage, if and when necessary, the concentration, registration date and e-version of packing-marking sample shall be indicated in the Official register.
3. Official register is a public document and for free availability of information it shall be obligatory to maintain it in e-form and provide its availability via Internet.

4. Entry of pharmaceutical product into Official register in accordance with the recognition mode of state registration of pharmaceutical product may be made as follows:
 - a) Proactively by the Agency, on the basis of information on pharmaceutical product authorized by other country's or intergovernmental regulatory state agency of pharmaceutical products for relevant market;
 - b) After administrative examination of homological identification document specified under Article 11¹⁰ of this Law, submitted by a Person concerned;
 - c) By a Person concerned after passing of procedure of notification about introduction of pharmaceutical product authorized for Georgian market with different packaging and marking for the first time.
5. Entry of pharmaceutical product into Official register in accordance with the national mode of state registration of pharmaceutical product shall be made only after the procedure specified under Article 11¹¹ of this Law.

Article 11⁷. Recognition mode of state registration of pharmaceutical product (*10.08.2009 #1586 be effective from October 15, 2009*)

1. Recognition mode of state registration of pharmaceutical product shall be applied to the pharmaceutical product, which is authorized by other country's or intergovernmental regulatory state agency of pharmaceutical products for relevant market.
2. Georgian government shall specify the list of other country's or intergovernmental regulatory state agencies of pharmaceutical products for the purpose of recognition of pharmaceutical product registered by them.
3. A Person concerned, during recognition mode of state registration of pharmaceutical product may be any person.
4. A Person concerned may carry out procedure for authorization of pharmaceutical product for Georgian market in accordance with the recognition mode of state registration of pharmaceutical product under this Law, notwithstanding the import purpose.
5. In case of introduction of pharmaceutical product in accordance with the recognition mode of state registration of pharmaceutical product for the first time, a Person concerned shall submit the following homological identification documents:
 - a) Certified translation of instruction in Georgian and instruction original in accordance with the regulations, established by the Ministry;
 - b) Pharmaceutical product:
 - b.a.) form;
 - b.b.) dosage

- b.c.) marking sample, which may be an original or represented as an e-version. The Agency shall have discretion authority regarding request form of marking sample; moreover, if a pharmaceutical product is not put into production, the Agency is obliged to accept e-version of marking sample and after putting of pharmaceutical product into production, the Agency may request replacement of e-version of marking sample with material form;
- b.d.) reference-standard in sufficient amount for conduction of 2 analysis (a Person concerned shall be entitled to represent active agent of pharmaceutical product);
- c) Term of authorization of pharmaceutical product for relevant market by other country's or intergovernmental regulatory state agency of pharmaceutical products;
- d) Unique number of authorization of pharmaceutical product for relevant market;
- e) Certificate of pharmaceutical product issued by other country's or intergovernmental regulatory state agency of pharmaceutical products, which may be issued for any market under control of other country's or intergovernmental regulatory state agency of pharmaceutical products, acknowledged by Georgian government;
- f) Instead of the certificate of pharmaceutical product referred to in sub-paragraph "e" of this paragraph it shall be permitted to submit the document equivalent to this certificate, which may be issued for any market under control of other country's or intergovernmental regulatory state agency of pharmaceutical products, acknowledged by Georgian government. Instead of the certificate of pharmaceutical product and document equivalent thereto it shall be permitted to submit their certified copies;
- g) Methods of analysis that may be printed out from publicly available source (pharmacopeia) or with indication of such source;
- h) Sample of pharmaceutical product – 2 standard packing or the amount, required for 2 analyses.
6. If any document referred to in paragraph 5 of this Article includes any other information required under homological identification documents, it shall not be necessary to submit it as a separate document.
7. The Agency shall conduct administrative examination of homological identification document and enter the information about pharmaceutical product into Official register within 7 business days.

Article 11⁸. Notification obligation of a Person concerned in case of first-time introduction of pharmaceutical product already authorized for Georgian market with different packing-marking
(10.08.2009 #1586 be effective from October 15, 2009)

1. For the first-time introduction of pharmaceutical product already authorized for Georgian market with different packing-marking, re-registration shall not be required. Such pharmaceutical product shall be authorized for Georgian market on the basis of regulations, specified under this Article for notification.
2. The notification shall include the following information:
 - a) certified translation of instruction in Georgian and instruction original in accordance with the regulations, established by the Ministry;
 - b) e-version of packing and marking of the pharmaceutical product sample;
 - c) certificate issued by a person having authorization for the distribution of pharmaceutical product in relevant country, which certifies authorization by other country's or intergovernmental regulatory state agency of pharmaceutical products, of medical product with such packing and marking for the market under its control. The certificate shall be accompanied with the identification information about person having authorization for the distribution of pharmaceutical product;
 - d) Unique number of authorization of pharmaceutical product for relevant market.
3. After receipt of notification:
 - a) the Agency shall be obliged to verify information submitted by a Person concerned;
 - b) the Agency, only taking into account of factual situation shall be entitled to reasonably reject first-time introduction of pharmaceutical product already authorized for Georgian market with different packing-marking and notify a Person concerned about it in writing;
 - c) failure to respond automatically means the consent of the Agency to first-time introduction of pharmaceutical product already authorized for Georgian market with different packing-marking.
4. In case of consent the Agency shall be obliged to enter information into Official register within 5 business days about pharmaceutical product authorized with different marking and packing for Georgian market.

Article 11⁹. Obligation of a Person concerned during circulation of a pharmaceutical product in Georgian market

1. Person concerned shall be obliged to keep the following during the period of circulation of pharmaceutical product in Georgian market:
 - a) Batch quality certificate;
 - b) Serial number of pharmaceutical product.
2. Documentation referred to in first paragraph of this Article shall be kept with the Person concerned during the period of possessing of pharmaceutical product by it.
3. After transferring of pharmaceutical product to other person, the responsibility for the fulfillment of obligations under this Article shall be rested to a person directly possessing a pharmaceutical product before its realization.

Article 11¹⁰. Verification of homological identification documents

1. After receipt of homological identification documents from a Person concerned the Agency shall be entitled to verify submitted documentation and transfer its copies without indication of trade secret containing information to the person authorized for the representation of the branch office of relevant foreign country, registered in accordance with Georgian legislation.
2. The Agency shall be obliged to transfer the copies referred to in first paragraph of this Article to the person authorized for the representation of the branch office of foreign country (permanent office) upon request.
3. The person authorized for the representation of the branch office of foreign country (permanent office) may verify obtained documentation and in case of any doubt regarding origin and quality of pharmaceutical product notify the Agency.
4. In case of notification from the person authorized for the representation of the branch office of foreign country (permanent office), the Agency shall be obliged to verify such information and take all measures specified under Georgian legislation in case of justified doubt.
5. After verification of homological identification documents the Agency shall enter information about pharmaceutical product into the Official register.
6. In case of expiration of authorization term of pharmaceutical product for Georgian market the Agency shall be obliged to cancel registration and withdraw it from the Official register.

Article 11¹¹. National mode of state registration of pharmaceutical product (*10.08.2009 #1586 be effective from October 15, 2009*)

1. State registration of pharmaceutical product by national mode shall be carried out as follows::
 - a) A person interested in state registration of pharmaceutical product by national mode may be a pharmaceutical product manufacturer or trade license holder. Person concerned shall submit to the Agency the application and attached documents. The application shall meet the requirements of Article 78 of General Administrative Code of Georgia;
 - b) Registration documents include administrative and scientific-technical parts; the Agency shall carry out their administrative and scientific-technical examination;
 - c) Administrative part of registration documents shall be submitted in Georgian and scientific-technical part – in Georgian, Russian or English in three copies; moreover, scientific-technical part may be submitted in e-version form;
 - d) The Agency no later than within 14 days shall inspect conformity of submitted registration documents with the requirements of this Article, i.e. carry out their administrative examination;
 - e) On the basis of affirmative conclusion of administrative examination, registration documents shall be subjected to further scientific-technical examination for the purpose of determination of standardization, quality, safety and therapeutic effectiveness of a pharmaceutical product;

- f) For elimination of defects revealed at administrative or scientific-technical examination stage, a Person concerned shall be given the term up to 2 months. In case of failure to eliminate defects within this period, the registration documents shall not be examined;
 - g) In case of necessity the Agency shall be entitled to additionally involve experts in examination of registration documents who shall be responsible for the objectiveness of their own conclusions.
2. Changes relating to the active agent, form, activity strength (dosage, concentration), administration method (way) and production of pharmaceutical product shall be considered as II category (with special significance) changes and require registration.
 3. Changes referred to in paragraph 21 of this Article shall be considered as I category (with relatively less significance) changes and require delivery of information about change to the Agency.
 4. In case of non-fulfillment of conditions referred to in paragraph 3 of this Article, such change shall be moved to II category changes and require registration.
 5. In case of changes of I and II category:
 - a) the following shall be submitted:
 - a.a) reasoning of change;
 - a.b) documentation certifying such change;
 - a.c) relevant updated registration documentation;
 - b) Registration of change shall not involve changing of registration term.
 6. For re-registration of pharmaceutical product, registration documentation shall be submitted no later than 2 months before expiration of registration term, otherwise, registration of pharmaceutical product shall be carried out by initial registration mode.
 7. During re-registration of pharmaceutical product a Person concerned shall be obliged to submit documentation referred to in paragraph 19 of this Article and data, publications and references on side effects of a pharmaceutical product for recent 5 years and attach the document certifying payment of registration fee.
 8. Counting of the term of registration procedure, including re-registration, registration of change and registration-listing shall be started from the moment of submission of registration documents in full.
 9. During registration procedure the Agency shall make a decision about registration, or rejection or approval of registration of change, including for registration of II category change - within 3 months, re-registration and registration-listing of pharmaceutical product – within 2 months, for registration of I category, “a” type change – within 10 days and for registration of II category, “b” type change - within 1 months and this shall be documented through administrative act.
 10. In case of rejection of pharmaceutical product registration, the Agency shall be obliged to immediately deliver justified refusal in writing to the Person concern. If case of failure to notify the Person concern about decision on rejection of registration within the terms specified in subparagraph “d” of first

paragraph and paragraph 9 of this Article, a pharmaceutical product shall be considered registered and the Agency shall be obliged to issue the document certifying authorization for Georgian market. The document certifying authorization for market shall be executed within 10 days after issuance of administrative act on registration. Administrative act and the document certifying authorization for Georgian market are equally valid documents.

11. If a pharmaceutical product is not put into production, the Agency shall be obliged to accept e-version of marking sample and after putting of pharmaceutical product into production the Agency may request replacement of the e-version of marking sample by material form.
12. The Agency shall cancel registration of pharmaceutical product in Georgia:
 - a) upon request of the Person concerned;
 - b) if there was revealed that pharmaceutical product has properties causing harm to humans and their descendants.
13. The agency, temporarily, until elimination of registration suspension cause, shall suspend registration of pharmaceutical product in Georgia:
 - a) upon request of the Person concerned;
 - b) in case of changing of any part of registration documents, which are not registered and/or listed in accordance with the established regulations and form.
14. The Agency shall cancel the document certifying authorization for Georgian market:
 - a) in case of cancellation of pharmaceutical product registration;
 - b) in case of necessity of issuance of a new document certifying authorization of pharmaceutical product for Georgian market.
15. Expiration of registration term shall involve cancellation of the document certifying authorization for Georgian market.
16. Circulation of pharmaceutical product at the territory of Georgia shall be permitted during 5 years after its registration and after expiration of registration term – up to expiration of its shelf life.
17. In case of change, circulation at the territory of Georgia of pharmaceutical product existing before such change is permitted up to the expiration of its shelf life.
18. Pharmaceutical substance, bulk and intermediate pharmaceutical products, pharmaceutical products prepared in accordance with the magistral and officinal prescriptions, allergen designed for specific natural person shall not require registration.
19. In administrative part of registration documents the following shall be submitted:
 - a. Application containing table of content for attached documents (with the indication of pages);
 - b. Original application about registration of pharmaceutical product to be represented in Georgia under national mode of state registration of pharmaceutical product;

- c. Original document certifying granting of representation authority by the Person concerned to natural person or legal entity;
 - d. Pharmaceutical product certificate in the form, recommended by World Health Organization (original) or in its absence—the document certifying manufacturing of pharmaceutical product in accordance with GMP standards or manufacturing license of pharmaceutical product, issued by authorized agency of manufacturing country;
 - e. Standard packing of pharmaceutical product to be registered with standard marking (or in e-version);
 - f. In case of registration of pharmaceutical product manufactured in Georgia - instruction in Georgian, and in case of registration of imported pharmaceutical product –certified translation of instruction in Georgian and original instruction in accordance regulations established by the Ministry.
20. In scientific-technical part of registration documents the following shall be submitted:
- a) For the registration of an innovative (new) pharmaceutical product:
 - a.a) Document, certifying registration of pharmaceutical product in manufacturing country, as well as in other countries (if any);
 - a.b) Chemical composition of pharmaceutical product, with the indication of all ingredients and their amounts per unit dose;
 - a.c) Monographs about active substance(s) (specification and methods of analysis);
 - a.d) Name and address of manufacturer(s) of active substance(s), bulk pharmaceutical product;
 - a.e) Monographs or references to the monographs represented in sets of international standards about non-active substance(s) (specification and methods of analysis);
 - a.f) Monographs about methods of analysis of pharmaceutical product including specification;
 - a.g) Pharmaceutical product manufacturing flow diagram;
 - a.h) Sample of pharmaceutical product – 2 standard packing plus amount, required for 2 analyses, with relevant quality certificate;
 - a.i) Reference standard(s) in the amount, sufficient for conduction of 2 analysis with relevant quality certificate;
 - a.j) Data on stability of pharmaceutical product;
 - a.k) Data form preclinical trial about specific pharmacological activity of pharmaceutical product, namely:
 - a.k.a) pharmacodynamic action;
 - a.k.b) mechanism of action
 - a.l) Date of pharmacokinetic study;
 - a.m) Data of toxicological study about acute, subacute and chronic toxicity;
 - a.n) Information on teratogenicity, embryotoxicity, mutagenicity, carcinogenicity and allergenicity;
 - a.o) Clinical data on pharmacokinetic, pharmacodynamics and side effects;

- a.p) Clinical trial report of pharmaceutical product;
- a.q) Summarized data on side effects;
- a.r) Experience in clinical application of pharmaceutical product:
 - a.r.a) Interaction with other pharmaceutical product;
 - a.r.b) publications and references;
- b) For the registration of generic and reproduced pharmaceutical product:
 - b.a) Chemical composition of pharmaceutical product, with the indication of all ingredients and their amounts per unit dose;
 - b.b) Relevant document certifying authorization of reproduction of pharmaceutical product on the basis of license (if any);
 - b.c.) Monographs or references to the monographs represented in sets of international standards about active substance(s) (specification and methods of analysis);
 - b.d) Name and address of manufacturer(s) of active substance(s);
 - b.e) Monographs or references to the monographs represented in sets of international standards about non-active substance(s) (specification and methods of analysis);
 - b.f) Monographs about methods of analysis of pharmaceutical product including specification;
 - b.g) Pharmaceutical product manufacturing flow diagram;
 - b.h) Sample of pharmaceutical product – 2 standards packing plus amount, required for 2 analysis, with relevant quality certificate;
 - b.i) Reference standard(s) in the amount, sufficient for conduction of 2 analysis with relevant quality certificate;
 - b.j) Data on stability of pharmaceutical product;
 - b.k) Information on bioequivalence or therapeutic equivalence, taking into account of a form and introduction way of pharmaceutical product (in accordance with the recommendations of World Health Organization);
 - b.l) Publications and references;
- c) For the registration of blood preparation:
 - c.a) document, certifying registration of blood preparation in manufacturing country, as well as in other countries (if any);
 - c.b) Chemical composition of blood preparation with the indication of all ingredients and their amounts per unit dose;
 - c.c) Monographs or references to the monographs represented in sets of international standards about active substance(s) (specification and methods of analysis);
 - c.d) Name and address of manufacturer(s) of active substance(s);

- c.e) Monographs or references to the monographs represented in sets of international standards about non-active substance(s) (specification and methods of analysis);
- c.f) Monographs about methods of analysis of blood preparation including specification;
- c.g) Blood preparation manufacturing flow diagram;
- c.h) Sample of pharmaceutical product – 2 standard packing plus amount, required for analysis, with relevant quality certificate approved by authorized agency;
- c.i) Reference standard(s) in the amount, sufficient for conduction of 2 analysis with relevant quality certificate;
- c.j) Data on stability of blood preparation;
- c.k) Description of closed container system;
- c.l) Information about effectiveness and safety of blood preparation (in the format, recommended by World Health Organization) with the description of methods used for inactivation of viruses;
- c.m) publications and references;
- d) For registration of immunobiological drug:
 - d.a) document, certifying registration of immunobiological drug in manufacturing country, as well as in other countries (if any);
 - d.b) Method and material of production of immunobiological drug; name and address of manufacturer(s);
 - d.c) Monographs or references to the monographs represented in sets of international standards about active substance(s) (specification and methods of analysis);
 - d.d) Monographs on methods of analysis of immunobiological drug, including specification;
 - d.e) Immunobiological drug manufacturing flow diagram;
 - d.f) Sample of immunobiological drug – 2 standard packing plus amount, required for analysis, with relevant quality certificate;
 - d.g) Data on stability of immunobiological drug;
 - d.h) Clinical data on effectiveness, safety and side effects of immunobiological drug;
 - d.i) Interaction with other pharmaceutical product;
 - d.j) Publications and references;
- e) For registration of paratherapeutic agent:
 - e .a) Chemical composition of paratherapeutic agent, with the indication of all ingredients and their amounts per unit dose;
 - e.b) Monographs about active substance(s) (specification and methods of analysis);
 - e.c) Name and address of manufacturer(s) of active substance(s);
 - e.d) Monographs or references to the monographs represented in sets of international standards about non-active substance(s) (specification and methods of analysis);
 - e.e) Monographs about methods of analysis of paratherapeutic agent, including specification;

- e.f) Paratherapeutic agent manufacturing flow diagram;
- e.g) Data on stability of paratherapeutic agent;
- e.h) Sample of paratherapeutic agent– 2 standards packing plus amount, required for analysis, with relevant quality certificate;
- e.i) Reference standard(s) (if required) in the amount, sufficient for conduction of 2 analysis with relevant quality certificate;
- e.j) Data on stability and effectiveness of paratherapeutic agent;
- f) For the registration of radiopharmaceuticals:
 - f.a) Document, certifying registration of radiopharmaceutical in manufacturing country, as well as in other countries (if any);
 - f.b) Composition of radiopharmaceutical, with the indication of all ingredients and their amounts per unit dose, specific or relative activity;
 - f.c) Monographs about active substance(s) (specification and methods of analysis);
 - f.d) Methods of production of active substance(s); name and address of manufacturer(s);
 - f.e) Monographs or references to the monographs represented in sets of international standards about non-active substance(s) (specification and methods of analysis);
 - f.f) Monographs about methods of analysis of radiopharmaceutical, including specification;
 - f.g) Radiopharmaceutical manufacturing flow diagram;
 - f.h) Quality certificate of radiopharmaceutical, approved by authorized agency;
 - f.i) Data on stability of radiopharmaceutical;
 - f.j) Data in effectiveness and safety of radiopharmaceutical (in case of therapeutic radiopharmaceutical);
 - f.k) Data on safety of radiopharmaceutical (in case of diagnostic radiopharmaceutical);
- g) For registration –listing of biologically active supplement (BAD) designed for physiological state:
 - g.a) Composition of BAD;
 - g.b) Method of analysis of BAD;
 - g.c) Sample of BAD – 2 standard packing plus amount, required for 2 analysis, with relevant quality certificate;
 - g.d) Free sale certificate (if any);
- h) For registration –listing of complementary therapeutic agent:
 - h.a) Full composition of complementary therapeutic agent;
 - h.b) Method of analysis of complementary therapeutic agent;
 - h.c) Sample of complementary therapeutic agent – 2 standard packing plus amount, required for 2 analysis, with relevant quality certificate;
 - h.d) Monographs about experience in usage of complementary therapeutic agent in medical practice, as well as about its effectiveness and safety with relevant references;

- h.e) Justification of action and purpose of complementary therapeutic agent on the basis of medicinal principles;
- i) For the registration of contraceptive mechanical agent (except for noninvasive contraceptive mechanical agent):
- i.a) Name and address of manufacturer(s) of contraceptive mechanical agent;
 - i.b) Standard, specifying quality assessment criteria;
 - i.c) 2 samples of contraceptive mechanical agent with relevant quality certificate;
- j) For registration-listing of dental products:
- j.a) Name, composition of dental product, information about its components and purpose;
 - j.b) Standard, specifying quality assessment criteria;
 - j.c) Quality certificate of dental product;
 - j.d) Information on dental product safety;
 - j.e) Sample of dental product;
- k) For registration- listing of diagnostic agents: test systems (according to nosologies), allergens (except for allergens designed for specific natural person), reagents (for clinical biochemistry and clinical chemistry) and serums:
- k.a) Purpose of diagnostic agent and application method (the list with the indication of catalogue number of manufacturer company and/or catalogue (if any));
 - k.b) Information on safety and effectiveness of diagnostic agent – in case of IN VIVO application;
 - k.c) Quality assessment criteria and information on stability of diagnostic agent (if required).
21. I category (with relatively less significance) changes:
- a) I category „a“ type changes:
- a.a.) Changes in manufacturing license
Requirements – updated manufacturing license shall be submitted;
 - a.b) Changing of pharmaceutical product name
Requirements:
 - a.b.a) New name shall not cause any misleading with respect to international unpatented name and/or registered pharmaceutical product name;
 - a.b.b) In case of general recognized name, the change is made with respect to pharmacopeial name or international unpatented name;
 - a.c) Changing of name and/or legal address of trade license holder –an entity with registration authority
Requirements – manufacturer shall not be changed;
 - a.d) Changing of active substance manufacturer
Requirement –Specification and quality control methods of substance shall correspond to the internationally recognized pharmacopeia;

a.e) Changing of inscription, coating or other markings, imprints on tablets and inscription on capsules
Requirements – new inscription shall not cause any misleading with respect to other tablets and capsules;

a.f) Changing of initial package marking, secondary package marking and design
Requirements – 2 new samples shall be represented;

a.g) Changing of amount of pharmaceutical product in package
Requirements – packing material shall not be changed;

b) I category „b“ type changes:

b.a) Changing of non-active substance

Requirements – shall not be changed:

b.a.a) similar functional properties;

b.a.b) for solid therapeutic forms – solubility level;

b.b) removal of paint or replacement of one paint with other;

b.c) addition, removal or changing of flavoring agents

Requirements – shall not be changed:

b.c.a) similar functional properties;

b.c .b) for solid therapeutic forms – solubility level;

b.d) changing of tablet cover mass or capsule cover mass

Requirements – solubility level shall not be changed;

b.e) qualitative changing of initial packing content

Requirements – offered packing material shall be equivalent to previous one, with relevant properties; changes shall not affect sterile products;

b.f) removal of any indication of application or of one of introduction ways

Requirements – safety of application and quality of preparation shall be maintained and justified by the retrospective preclinical trial data ;

b.g) Insignificant changes in production of active substance

Requirements – Undesirable changes shall not be made in the specification of substance, as well as, physical properties of substance shall not be changed, no new additives shall be added or level of additives shall not be changed that requires conduction of study for establishment of finished product safety;

b.h) Changing of series/batch amount of active substance

Requirements – Data analysis on control of substance shall indicate that manufacturing process uniformity has not been disturbed and/or physical properties of substance have not been changed;

b.i) Insignificant changes in pharmaceutical product manufacturing

Requirements – Specification of preparation shall not be changed; new technical process shall provide manufacturing of identical preparation in terms of quality, effectiveness and safety;

b.j) Changing of finished product production batch volume

Requirements – manufacturing process uniformity shall not be disturbed;

b.k) Changing of pharmaceutical product specification

Requirements –Specification shall be improved or new tests for the preparation quality control shall be added and range of variation of parameters shall be specified;

b.l) Synthesis or recovery of supplements, which are described in initial registration documentation and are not indicated in pharmacopeia

Requirements –Specification, composition of additives or their level shall not be changed that requires conduction of study for establishment of finished product safety; as well as, physical-chemical properties of finished product shall not be changed;

b.m) Changing of specification of pharmaceutical product supplement (except for vaccines adjuvant)

Requirements – Specification shall be improved or new tests for the preparation quality control shall be added and range of variation of parameters shall be specified;

b.n) Prolongation of shelf life of pharmaceutical product indicated during licensing

Requirements –Data on stability of preparation shall be submitted according to protocol approved during obtainment of trade license; the data shall indicate that the shelf life has not been changed; it shall not exceed 5 years;

b.o) Changing of shelf life after opening of packing for the first time

Requirements – Analysis of data on preparation stability shall indicate that the shelf life of preparation has not been reduced in accordance with the specification approved during obtaining of trade license;

b.p) Changing of shelf life of pharmaceutical product after its recovery

Requirements – Analysis of data on preparation stability shall indicate that the shelf life of preparation has not been reduced in accordance with the approved specification;

b.q) Changing of storage conditions

Requirements – Analysis of data on preparation stability shall indicate that the shelf life of preparation has not been reduced in accordance with the specification approved during obtaining of trade license. Data on stability in accordance with the specification approved during obtaining of trade license shall be submitted;

b.r) Changing of test method of active substance

Requirements –Results of method validation (inspection of reliability) shall indicate that the new test method is equal to previous one;

b.s) Changing of quality control method of pharmaceutical product

Requirements –Preparation specification shall not be changed; results of method validation shall indicate that the new method of quality control is equal to previous one;

b.t) Relevant changing of amendment made to pharmacopeia

Requirements –Change shall be made only for the purpose of implementing of new amendment to pharmacopeia;

b.u) Changing of test method for non-pharmacopeial supplement

Requirements – Results of method validation shall indicate that the new test method is equal to previous one ;

b.v) Changing of test method for initial packing

Requirements – Results of method validation shall indicate that the new test method is equal to previous one;

b.w) Changing of test method for induction device

Requirements – Results of method validation shall indicate that the new test method is equal to previous one;

b.x) Changing of initial packing form

Requirements –Quality and stability of finished product placed into packing, as well as, interaction of packing material and preparation shall not be changed;

b.y) Changing of size and average weight of tablets, capsules and suppositories without qualitative changing of their content

Requirements – solubility level shall not be changed.

22. II category changes requiring registration:

a) Changing of pharmaceutical product form, strength and administration method:

a.a) Changing of bioavailability;

a.b) Changing of pharmacokinetics;

a.c) Changing of pharmaceutical product efficiency;

a.d) Changing of therapeutic form or addition of new therapeutic form;

a.e) Addition of new application method;

b) Changing of active substances:

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

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

b.c) Changing of amount of active substance;

b.d) Replacement of active substance with other salt (ethereal complex) derivative (by components with the same therapeutic properties), other isomer, isomer mix or isolated isomer mix;

b.e) Replacement of biological substance or biotechnological product with other substance or product having different molecular structure; carrier modification, which is used for production of antigen material;

c) Changing of therapeutic indications:

c.a) Addition of indication of administration in other field of therapy (treatment, prophylaxis , diagnostics);

c.b) Removal of indication of administration in other field of therapy (treatment, prophylaxis , diagnostics);

d) Changing of manufacturing place.

23. Amount of fee for state registration of pharmaceutical product under national mode shall be specified in accordance with this Law.

Article 11¹². Sample of pharmaceutical product (*10.08.2009 #1586 be effective from October 15, 2009*)

1. Sample of pharmaceutical product is the possibility of comparison with pharmaceutical product existing in distribution chain for the purpose of conduction of random inspection by the Agency.
2. The Agency shall use sample of pharmaceutical product for visual comparison of pharmaceutical product marking and during laboratory inspection.
3. Rules for replacement of pharmaceutical product samples, kept by the Agency shall be specified by the Minister.

Article 11¹³. Exceptional cases of import of pharmaceutical product with evasion of authorization modes for Georgian market (*10.08.2009 #1586 be effective from October 15, 2009*)

Pharmaceutical product with evasion of authorization modes for Georgian market may be imported for non-commercial purposes in the following cases:

- a) For preclinical and clinical trials;
- b) For registration, in the form of sample;
- c) For individual needs of natural person;
- d) For exhibition, symposium, conference, forum and congress - in the form of sample, without distribution authority;
- e) For re-export;
- f) For the purpose of storage in customs warehouse/customs terminal and/or for including in transit commodity transaction; (*27.03.2012. #5961*)
- g) As an bulk pharmaceutical product designed for local production;
- h) In special cases (Acts of God, mass injury of population, epidemic, rare disease) for humanitarian aid purposes, as well as in case of special public interests under consent of the Ministry. (*17.12.2010. #4125*)

Chapter V. Manufacturing of pharmaceutical product

Article 12. Manufacturing of pharmaceutical product

1. Manufacturing of pharmaceutical product shall be subjected to authorization mode.
2. Manufacturing of pharmaceutical product, which is not registered in Georgia, shall be permitted for its registration, its preclinical and clinical trials, export.
3. Manufacturing permission for pharmaceutical product shall be issued by the Agency.
4. Georgia selectively acknowledges the list of international, regional and national GMP (good manufacturing practice) standards, which shall be acknowledged by the Georgian government.

5. Authorization conditions for pharmaceutical product shall be specified in accordance with the Georgian legislation.
6. For the purpose of this Law, the authorized drugstore, which prepares pharmaceutical product on the basis magistral or officinal formula, as well as the drugstore of such medical institution, which carries out prepackaging of pharmaceutical product in required amounts for its usage in health-care institutions, shall not be considered as a pharmaceutical product manufacturing and no permission shall be required.
7. The person manufacturing pharmaceutical product batches shall be responsible for the safety, quality and effectiveness of manufactured pharmaceutical product.
8. Introduction of national GMP standard for manufacturing shall be carried out by the Georgian government in stages, in accordance with the risk management principle
Article 13. Repealed. (18.12.2001. #1119. Sakanonmdeblo Matsne #36)
Article 14. Repealed (10.08.2009 #1586 be effective from October 15, 2009)
Article 15. Repealed (18.12.2001. #1119. Sakanonmdeblo Matsne #36)

Chapter VI. Sale of pharmaceutical product (10.08.2009 #1586 be effective from October 15, 2009)

Article 16. Wholesale and retail sale of pharmaceutical product

1. Retail sale of pharmaceutical product shall be made by authorized drug store, drug store (specialized trade object), and retail facility, and in cases, specified under the Georgian legislation – personnel with pharmaceutical education or a natural person, the entity of independent medical activity.
2. Authorized drug store shall be subjected to authorization control and it shall be entitled to sell pharmaceutical products, included into first, second and third groups, as well as to prepare pharmaceutical product in accordance with the officinal or magistral prescription.
3. Drug store (specialized trade object) shall be entitled to sell pharmaceutical products, included into second and third groups, and retail facility – only the pharmaceutical products included into third group; moreover, there may be separated, isolated drug store (specialized trade object) with independent entrance, as well as a drug store, located into retail facility (specialized trade object) in the form of isolated area.
4. For the purpose of improvement of population access to the pharmaceutical products, personnel with pharmaceutical education or a natural person, the entity of independent medical activity shall be entitled to carry out retail sale of pharmaceutical product (except for the pharmaceutical products under special control) in villages and settlements.
5. Commencement and finishing of pharmaceutical product wholesale and retail sale shall be subjected to obligatory notification of the Agency; the form and rules of notification shall be approved by the Minister.
6. Application of such pharmaceutical product under special control by a medical service provider, which is the part of medical service, shall not require authorization.

7. Authorization conditions of authorized drug store for sale of pharmaceutical product under special control and the rule of selling of such product shall be specified in accordance with the Georgian legislation.
8. It shall not be permitted to sell pharmaceutical product at market and fair, as well as from open-type retail facility and non-stationary retail place.
9. It shall not be permitted to sell pharmaceutical products of first and second groups in accordance with Article 11² of this Law to juveniles. (30.07.2013 #907).
10. Selling of the following medical agents without prescription shall not be permitted:
 - a) Pharmaceutical products, included into first group;
 - b) Pharmaceutical products, included into second group.

Article 17. Requirements for pharmaceutical product distributor (10.08.2009 #1586 be effective from October 15, 2009)

1. Principle of regulation of pharmaceutical product distribution shall be the provision of storage and dispensing conditions and due maintaining of documentation required for registration of batch of sold product.
2. Pharmaceutical product distributor shall be obliged to register pharmaceutical product batch designed for sale by it.
3. Pharmaceutical product distributor shall be obliged to introduce modern technologies for storage of pharmaceutical product and provide storage of pharmaceutical product and its further realization in such conditions that protect the product against negative impact of ambient factors (temperature, humidity).
4. Pharmaceutical product distributor shall be obliged to store pharmaceutical product in accordance with sanitary-hygienic/technical conditions, specified in the instruction of relevant pharmaceutical product.
5. Sanitary-hygienic/technical conditions for drug store (specialized trade object) and retail facility shall be specified by the Ministry in accordance with this Article.
6. In retail facility selling of pharmaceutical product shall be permitted if:
 - a) pharmaceutical product is displayed in place specially designed for it by special indication in such a way that it is separated from other products and it is possible to clearly distinguish such pharmaceutical product from other products;
 - b) for drug store (specialized trade object) located in retail facility there is allocated independent, isolated area for pharmaceutical product distribution, and moreover if distribution of pharmaceutical product in such drug store (specialized trade object) is carried out by the responsible personnel with medical or pharmaceutical education (hereinafter referred to as the Responsible personnel), who are not allowed to make simultaneous supervision over other products and/or execution of other work;
 - c) in accordance with the storage conditions indicated in the instruction, pharmaceutical product is protected against negative impact of ambient factors (including direct sunlight, humidity, temperature etc.).

- d) distribution, storage and placement of pharmaceutical product is carried out with full observance of sanitary-hygienic conditions.
- 7. Pharmaceutical product included in second group shall not be available for customers without Responsible personnel, and pharmaceutical product included in third group shall be available for customers in accordance with the requirements, referred to in this Law without Responsible personnel.
- 8. Expired and unfitted pharmaceutical product, before its disposal shall be kept independently, isolated from other pharmaceutical products.
- 9. If pharmaceutical product distributor has justified doubts that pharmaceutical product does not have authorization for Georgian market, it is adulterated, rejected, unfitted, expired:
 - a) the Distributor shall be obliged to:
 - a.a) suspend distribution of suspicious pharmaceutical product;
 - a.b) immediately notify the Agency about it.
 - b) The Agency shall be obliged to:
 - b.a) verify information from the Distributor;
 - b.b) notify the Distributor within reasonable period of time if the doubt is not proved;
 - b.c) provide supervision of withdrawal of pharmaceutical product from wholesale and retail sale network if it is identified that the pharmaceutical product batch is unauthorized for Georgian market, adulterated, rejected, unfitted, expired.

Article 17¹. Forfeiture and disposal of pharmaceutical product (*10.08.2009 #1586 be effective from October 15, 2009*)

Pharmaceutical product shall be subjected to forfeiture by the Agency and disposal at the cost of product owner in accordance with the regulations, approved by the Ministry or on the basis of acknowledged guidelines, if:

- a) it is unauthorized for Georgian market, adulterated, rejected, unfitted, expired;
- b) it is found out that as result of unforeseen mistake made at manufacturing stage, it is unduly marked and/or may create threat to customer's life or health.

Chapter VII. Repealed (*10.08.2009 #1586 be effective from October 15, 2009*)

Chapter VIII. Substances, agents under special control and their pharmaceutical forms

Article 20. Substances, agents under special control and their pharmaceutical forms

- 1. In the field of public health and in accordance with the state policy for the provision of public order, narcotic drugs and their containing agents, poisons and poison-containing agents, separate psychotropic and potent agents shall be subjected to special state control.

2. List of substances, agents under special control and their pharmaceutical forms shall be in accordance with the international conventions in this field.
3. The Ministry of Labor, Health and Social Affairs of Georgia when required shall supplement these lists taking into account local narcological situation and practice of law enforcement and investigation agencies.

Article 21. Control of legal circulation of substances, agents under special control and their pharmaceutical forms

1. Manufacturing and legal circulation of substances, agents under special control and their pharmaceutical forms shall be governed in accordance with the Georgian legislation.
2. Annual demand on narcotic drugs, relevant quotas, including export and import of such substances shall be specified by the Ministry of Labor, Health and Social Affairs of Georgia.
3. All persons involved in legal circulation of substances, agents under special control and their pharmaceutical forms shall deliver information to the Ministry of Labor, Health and Social Affairs of Georgia in accordance with established rule. (12.02.2010 #2560)

Article 22. Circulation of radioactive therapeutic agents

Rules for packing, storage, import, shipping and transportation, dispensing, application and disposal of radioactive preparations used in medical practice shall be specified in accordance with the Georgian legislation.

Chapter IX. Repealed (10.08.2009 #1586 be effective from October 15, 2009)

Chapter X. Monitoring of side effects of medication

Article 26. Monitoring of side effects of medication

1. Attending doctors of therapeutic- prophylaxis network, therapeutic service specialist of patient care institutions and structures of the Ministry of Labor, Health and Social Affairs of Georgia shall participate in unified system of monitoring of side effects of medication. Repealed (18.12.2001 #1191)
2. Integrated coordination of monitoring system and analysis of obtained informational material shall be made by the State Regulation Agency for Medical Activities, which shall:
 - a) collect information about side effects of medication, analyze and summarize it;
 - b) exchange such information with medical services of other countries and World Health Organization.
 - c) organize examination of obtained data and prepare recommendations about manufacturing of medication, its withdrawal from circulation and cancelation of its registration certificate;
 - d) study incompatibility and interaction of medications in stages, summarize information on pharmaceutical products, prepare informational material. (13.08.2004 #337)

3. The rule and order of formation of information flow from therapeutic network about side effects of medication shall be developed and approved by the Ministry of Labor, Health and Social Affairs of Georgia. (13.08.2004 #337)
4. Entities of pharmaceutical product circulation and application shall be obliged to deliver to the State Regulation Agency for Medical Activities the information about all cases regarding side effects of medication and peculiarities of other interaction of pharmaceutical product, which are not indicated in patient information leaflet. (13.08.2004 #337)

Chapter XI. Repealed (24.09.2009 #1703 be effective from October 16, 2009)

Chapter XII. Repealed (10.08.2009 #1586 be effective from October 15, 2009)

Chapter XII¹. Responsibility in the field of pharmaceutical product circulation

Article 37¹. Basis of responsibility relating to the quality and safety of pharmaceutical product (10.08.2009 #1586 be effective from October 15, 2009)

1. Responsibility of persons involved in pharmaceutical product circulation shall be classified in accordance with the following basis:
 - a) Market authorization holder and the state shall be responsible for the safety, quality and effectiveness of pharmaceutical product authorized for Georgian market under national mode of state registration of pharmaceutical product;
 - b) The state shall be responsible for the safety, quality and effectiveness of pharmaceutical product authorized for Georgian market under recognition mode of state registration of pharmaceutical product;
 - c) Pharmaceutical product batch manufacturer shall be responsible for correspondence of pharmaceutical product authorized for Georgian market under national mode of state registration of pharmaceutical product, with the documentation submitted during registration;
 - d) If after putting of imported pharmaceutical product authorized for Georgian market in marketing network, properties of pharmaceutical product are changed due to which it does not meet the safety and quality standards, Importer and/or representative of relevant unit of marketing network shall be responsible. Guiltiness shall be established in accordance with the regulations, specified under Georgian legislation;
 - e) For violation of pharmaceutical product wholesale and retail sale conditions, which includes all transactions relating to purchase, storage, supply and sale of pharmaceutical product responsibility shall be imposed to pharmaceutical product distributor.
2. Responsibility of a person for violations revealed during pharmaceutical activity shall be specified in accordance with this Law and the Georgian legislation.
3. The protocol for administration violations specified under this Law shall be drawn up by the agency (official) authorized by the Ministry (24.09.2009 #1703 be effective from October 16, 2009)

Article 37². Illegal pharmaceutical activity

1. Activity without permission of pharmaceutical manufacturing, export or import of pharmaceutical product under special control, authorized drug store, clinical trial of pharmaceutical product shall involve imposing of fine in the amount of 8000 GEL.
2. For the same, repeated act the fine in the amount of 16000 GEL shall be imposed.

Article 37³. Violation of authorization conditions of pharmaceutical manufacturing, export or import of pharmaceutical product under special control, authorized drug store, clinical trial of pharmaceutical product (30.07.2013 #907)

Violation of authorization conditions of pharmaceutical manufacturing, export or import of pharmaceutical product under special control, authorized drug store, clinical trial of pharmaceutical product shall involve imposing of fine in the amount of 2000 GEL.

Article 37⁴. Violation of rules of pharmaceutical activity

1. Preparation and distribution of pharmaceutical product by unauthorized personnel (personnel without pharmaceutical education/entity without authority of independent medical activity) shall involve imposing of fine in the amount of 4000 GEL with the seizure of law-violation object.
2. Violation of pharmaceutical product preparation rules, violation of storage conditions, specified under instruction shall involve imposing of fine in the amount of 2000 GEL with the seizure of law-violation object.
3. Violation of rules of pharmaceutical product distribution (except for pharmaceutical products included into first group under Article 11² of this Law) shall involve imposing of fine in the amount of 500 GEL.
4. The act specified under paragraph 3 of this Article, committed repeatedly shall involve imposing of fine in the amount of 1000 GEL.
5. Violation of distribution rules of pharmaceutical product included into first group under Article 11² of this Law shall involve imposing of fine in the amount of 6000 GEL.
6. The act specified under paragraph 5 of this Article, committed repeatedly shall involve imposing of fine in the amount of 12000 GEL.
7. Distribution of substandard, expired, unfitted pharmaceutical product shall involve imposing of fine in the amount of 6000 GEL with the seizure of law-violation object.
8. Circulation of adulterated pharmaceutical product in Georgian market shall involve imposing of fine in the amount of 20000 GEL, with the seizure of law-violation object.
9. Violation of rules of registration, manufacturing, standardization, marking, shipping and transportation, import and export, re-export, batch registration and disposal shall involve imposing of fine in the amount of 1600 GEL, with the seizure of law-violation object.
10. The same act specified under paragraph 9 of this Article, committed repeatedly shall involve imposing of fine in the amount of 4000 GEL, with the seizure of law-violation object.

Article 37⁵. Circulation of pharmaceutical product with evasion of authorization modes for Georgian market and/or without authorization for Georgian market (30.07.2013 #907)

1. Circulation of pharmaceutical product with evasion of authorization modes for Georgian market and/or without authorization for Georgian market pharmaceutical product shall involve imposing of fine in the amount of 6000 GEL, with the seizure of law-violation object.
2. The same act committed repeatedly shall involve imposing of fine in the amount of 12000 GEL, with the seizure of law-violation object.

Article 37⁶. Violation of rules of pharmaceutical product advertisement (30.07.2013 #907)

Violation of rules of pharmaceutical product advertisement (with respect to advertiser, as well as executor) shall involve imposing of fine in the amount of 2000 GEL.

Article 37⁷. Commencement and finishing of pharmaceutical product distribution without delivery of obligatory notification to the Agency

1. In accordance with paragraph 5, Article 16 of this Law commencement and finishing of pharmaceutical product distribution without delivery of obligatory notification to the Agency shall involve imposing of fine in the amount of 2000 GEL.
2. The same act committed repeatedly shall involve imposing of fine in the amount of 4000 GEL.

Article 37⁸. Changing of pharmaceutical product packing-marking without registration or delivery of obligatory notification to the Agency

Changing of pharmaceutical product packing-marking without registration or delivery of obligatory notification to the Agency shall involve imposing of fine in the amount of 2000 GEL, with suspension of distribution up to the elimination of law-violation.

Article 37⁹. Selling of pharmaceutical product included into first or second group in accordance with Article 11² of this Law to juvenile

Selling of pharmaceutical product included into first or second group in accordance with Article 11² of this Law to juvenile shall involve imposing of fine in the amount of 500 GEL.

Chapter XIII. Transitional and final provisions (title 30.07.2013 #907)

Article 38. Transitional and final provisions (title 30.07.2013 #907)

1. Paragraph 6 of Article 14 of this Law be effective for medication to be put into retail circulation, which shall be registered or re-registered in accordance with rules established at the territory of Georgia from January 1, 2003 (25.12.2002 #1848).
2. Repealed (10.04.2002 #1356)
 - 2¹. Paragraph 9 of Article 16 of this Law be effective from January 1, 2014 and subparagraph “b” of paragraph 10 – from September 1, 2014 (25.12.2013 #1862)
3. Paragraph 11 of Article 11 of this Law be effective from January 1, 2006. (11.10.2005 #1918)



4. Within three months after entering into force of this Law, the Ministry of Agriculture of Georgia shall provide: *(18.06.2008 #23)*
 - a) Development of rules for control of state registration, re-registration or cancellation of registration and quality/safety for Georgia-manufactured or imported veterinary preparations (agents);
 - b) Approval of forms of registration certificates for veterinary preparations;
4. Articles 6, 7 and 8 of this Law be invalidated from December 15, 2009. *(10.08.2009 #1586 be effective from October 15, 2009)*

Eduard Shevardnadze

The President of Georgia

Tbilisi

April 17, 1997

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