Pharmaceutical Product Regulation in Georgia
1. Pharmaceutical Product regulation overview

Under the Georgian law a pharmaceutical product is a medicine or a physiologically active sub-
stance derived naturally or by synthesis, or their combination, and allowed for medical use. These
include complementary medicinal products, biologically active additives and registered para-thera-
peutic products.

Main regulatory body with respect to pharma products is LEPL Regulation Agency for Medical and
Pharmaceutical Activities ("Agency") under the Ministry of Internally Displaced Persons from Oc-
cupied Territories, Labour, Health and Social Affairs ("Ministry of Health").

The Ministry of Health determines state policy regarding the pharmaceutical products; establishes
procedures related to market recognition of such products, determines rules on destruction of falsi-

fied/dated/faulty products etc.

Agency enforces the rules established by the Ministry of Health through marketing authorizations,
managing the registry of pharma products, ensuring removal from the market and destruction of
falsified/dated/faulty products etc.

2. Marketing Authorization for Pharmaceutical Products

In order for a pharmaceutical product to be sold on a Georgian market it needs a marketing au-

thorization. Such authorization means that pharmaceutical product complies with specific require-

ments defined by the legislation of Georgia.

Pharmaceutical products that have marketing authorization are entered in the Agency registry.¹

The marketing authorization is obtained either through national state registration or recognition

track.

Marketing authorization has a validity term, the extent of which depends on the regime of reg-

istration. Placement of the product on the market is allowed throughout the validity term of its
authorization. After the expiry of such term, authorized person is allowed to apply for the renewed
registration.

Should the validity term of the marketing authorization expire, the product is allowed on the market
until the product expiry date. After expiry of both: registration validity term and expiry term – the
product is removed from the market.

¹ http://apps.ssa.gov.ge/recepti/Camlebi
2.1. The national regime of state registration ("national registration")

In case of national registration, a manufacturer or license holder of a pharmaceutical product applies to the Agency together with the administrative and scientific-technical documents.

**Administrative documents** that need to be submitted are as follows:

a) Application with respective power of attorney or other document confirming authority of an applicant;

b) An original Certificate of Pharmaceutical Product in the form as recommended by the World Health Organization; in case such is not available - a document certifying that the pharmaceutical product has been manufactured according to the Good Manufacturing Practices standard ("GMP"), or a pharmaceutical product manufacturing licence issued by an authorised body of the manufacturing country; in case of dental materials, invasive contraceptive mechanical means and diagnostic means it is permissible to present ISO certificate of production/EC certificate or certificate of free sale;

c) Standard form of packaging of the pharmaceutical product (either sample or electronic form);

d) In case the product is manufactured in Georgia – instruction of usage in Georgian language; otherwise - instruction of usage in original language with the respective notarized translation in Georgian.

e) Receipt confirming the payment of registration fee²;

Scientific-technical documents are different depending on the type of pharmaceutical product such as Innovative Product; Reproduced and Generic Product; Blood Drugs; Immunobiological Drugs; Paramedical Products; Radiopharmaceuticals; Biologically Active Additive (BAA); Complementary Medicine Products; Contraceptive Means; Dental Products; Diagnostical Means.

By scientific-technical documents the applicant describes to the Agency the effects and methods of treatment via the product being registered.

Validity term of marketing authorization of pharmaceutical product in case of national regime consists of 5 years.

²The exact amount of fee depends on the type of product and generally varies from GEL 200 to GEL 500. However, the fee for registration of innovative product amounts GEL 2500
2.2. The recognition regime of state registration

Recognition regime is applicable to the pharmaceutical products already registered in the specific list of countries. Such list is established by the decree of the Government of Georgia. Pharmaceutical products registered by of the listed countries may obtain marketing authorization through a simplified procedure.

Documents/information to be submitted for the recognition regime is as follows:

a) patient information leaflet in both original and Georgian languages;

b) the following information on a product:
   - the form;
   - the dosage;
   - a labelling sample, in the original or an electronic form;
   - a reference standard in the quantity sufficient to conduct 2 tests (an interested person may submit an active substance of the respective pharmaceutical product instead of a reference standard);

c) the validity period of marketing authorisation in the respective market granted by a state body regulating pharmaceutical products in a foreign country or internationally;

d) a unique number of the marketing authorisation of a pharmaceutical product in the respective market;

e) a Certificate of a Pharmaceutical Product (“CPP”) issued by a state body regulating pharmaceutical products in a foreign country or internationally, which may have been issued for any market under the control of a state body regulating pharmaceutical products in a foreign country or internationally, recognised by the Government of Georgia;

f) instead of a CPP referred to in paragraph 5 (e), a document equivalent to a CPP may be submitted, which may have been issued for any market under the control of a state body, regulating pharmaceutical products in a foreign country or internationally, recognised by the Government of Georgia. Duly attested copies of a CPP or a document equivalent to the CPP may be submitted;

g) analysis methods that may be printed from a publicly available source (the pharmacopoeia), with reference to the source;

h) a sample of a pharmaceutical product - 2 standard packages or a quantity sufficient to conduct 2 tests.

Validity term of registration for recognised products shall be the term established by the above-stated foreign regulatory body, however it shall not exceed 5 years in Georgia.
3. Classification of Pharmaceutical Products

Pharmaceutical products are classified into three groups:

a) **First group** - includes pharmaceutical products which fall under special control;

b) **Second group** - includes pharmaceutical products, that may cause significant damage to a person’s life/health and/or which may not be consumed without following a special instruction and which is issued only with a medical prescription.

c) **Third group** - includes pharmaceutical products, which may be consumed without a prescription.

Pharmaceutical products are attributed to the first or third group according to the order of the Ministry of Health, whereas the products are automatically attributed to the second group if they do not fall under the order of the Ministry of Health.

Selling and/or advertising the pharmaceutical products of first and second group without medical prescription is prohibited.

4. Manufacturing of Pharmaceutical Products

- Manufacturing of pharmaceutical products (except narcotic drugs) in Georgia is subject to pharmaceutical manufacturing permit (“Permit”) issued by the Agency.

- It is mandatory to get the Permit for one of the following activities:
  
  ✔ Manufacturing (complete manufacturing-technological process) of pharmaceutical/pharmacological/bulk pharmaceutical products and pharmaceutical substance;
  
  ✔ Conducting one or more operations/activities of the complete manufacturing-technological process of pharmaceutical/pharmacological products and pharmaceutical substance;
  
  ✔ Manufacturing of pharmaceutical products for export purposes, that are not allowed on the Georgian market.

- Manufacturing of narcotic drugs and non-registered pharmaceutical products is prohibited.
5. Regulation of Good Manufacturing Practice

- Georgia recognizes the following GMP standards:
  - WHO – World Health Organization;
  - EC – European Commission;
  - PIC/S GMP - Pharmaceutical Inspection Co-operation Scheme;
  - FDA - Food and Drug Administration

- Georgia recognizes EC GMP as its national standard.

- From 1 July 2019, the Permit is issued only if GMP requirements are met.

- Those manufacturers who already have the Permit must ensure GMP compliance from 1st January 2022.

6. Required documents to obtain the Permit

- The Permit seeker shall submit the application form to the Agency with the following documents/information:

  ✓ Extract from Registry of Entrepreneurs and Non-Entrepreneurial (Non-Commercial) Legal Entities;
  ✓ Extract from the Public Registry regarding the real estate, where the manufacturing is planned;
  ✓ Information regarding qualified persons responsible for quality control and manufacturing process;
  ✓ Diplomas of the responsible persons;
  ✓ Main dossier of pharmaceutical manufacturing (Site Master File) in accordance with EC GMP, recognized as national standard in Georgia;
  ✓ Information regarding material technical base to ensure quality control;
  ✓ Information regarding contracting laboratories (if any);
  ✓ Information regarding accessibility of technical agreement;
  ✓ In case manufacturing of pharmaceutical products being under special control, detailed information regarding the person, who is responsible for such manufacturing;
  ✓ Receipt confirming payment of the fees.
7. Procedure at the Agency

- The Agency checks the application and enclosed documents to be in accordance with the requirements of the Permit.

- After review of the documents the Agency decides to either:
  - Reject the application and do not issue the Permit or
  - Conduct the inspection of the premises, where manufacturing is planned.

- The purpose of inspection of the premises is to check:
  - The authenticity of the data presented by the applicant and
  - Compliance with the Permit terms (GMP standard).

- The Agency grants the Permit if the authenticity of the data provided to the Agency and compliance with GMP standards is proved.

- The decision on issuance or rejection of the Permit is made within 20 days from the date of application. If the decision is not made within this term, the Permit is deemed to be granted.

8. Realization of pharmaceutical products

Retail sale of a pharmaceutical products may be carried out by:

- authorised pharmacies
- pharmacies (specialised retail outlet),
- retail outlets
- natural persons acting as an entity of independent medical practice.

Authorised pharmacies may sell pharmaceutical products of all three groups, however opening such pharmacy requires special permit issued by the Agency. In addition, authorised pharmacies are entitled to produce pharmaceutical products in accordance with official or magistral recipes.

Pharmacies (specialised retail outlet) may sell pharmaceutical products of second and third groups. While no special permit or license is required for opening pharmacy, a notification (filled in in an established format of the Ministry of Health) is submitted to the Agency upon opening or closing such pharmacy.

Retail outlets may also sell pharmaceutical products of third group, without obtaining permit or license. However, a notification (filled in in an established format of the Ministry of Health) is submitted to the Agency upon commencement or completion of such activities.

Natural persons acting as an entity of independent medical practice may only carry out retail sale of
pharmaceutical products in village or urban-type areas. Notification (filled in in an established format of the Ministry of Health) is also submitted to the Agency upon commencement or completion of such activities.

Wholesale of pharmaceutical products does not require permit or license, however upon commencement or completion of such activities, relevant notifications (filled in in an established format of the Ministry of Health) are submitted to the Agency.
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