Admission of pharmaceutical products into the Georgian market may be granted by way of state registration through:

(a) recognition regime; and

(b) national regime.

Pharmaceutical products are deemed admitted into the market if they are registered with the Departmental Registry kept by the Agency of State Regulation of Medical Activities at the Ministry of Labor, Health and Social Protection of Georgia (the Agency).

**State Registration through Recognition Regime**

Recognition regime may be applied for both innovative and generic pharmaceutical products already admitted into the relevant market by an intergovernmental pharmaceutical products regulatory body or a regulatory body of foreign countries.

The list of the above regulatory bodies is determined by the Resolution No. 188 of the Government of Georgia, dated 22 October 2009, which among others includes the European Medicines Agency (EMEA), as well as a regulatory body of the Federal Republic of Germany.

It should be noted that for purposes of recognition regime the person concerned may be any natural or legal person wishing to register/admit into the market certain pharmaceutical product notwithstanding the aim of import.

The person concerned importing innovative or generic pharmaceutical product for the first time shall submit to the Agency:

- an application\(^1\);

- document evidencing payment of registration fee \(^2\);

as well as the following homology identification documents:

\(^1\) The form of application (Form No. 1) is approved by the Order No. 344/n of the Minister of Labor, Health and Social Protection of Georgia, dated 23 October 2009.

\(^2\) Such fee amounts to 500 Georgian Lari.
the original instruction ³ along with authorized Georgian translation thereof;

form, dosing and original/electronic label sample of the pharmaceutical product as well as reference standard for two tests or

active substance of the respective pharmaceutical product;

the period of admission of the pharmaceutical product into the respective market by an intergovernmental pharmaceutical products regulatory body or a regulatory body of foreign countries;

unique (authorization) number of admission of the pharmaceutical product into the respective market;

certificate of the pharmaceutical product issued by an intergovernmental pharmaceutical products regulatory body or a regulatory body of foreign countries or other equivalent document ⁴;

test methods which may be printed out from publicly available source (pharmacopoeia ⁵) along with reference to such source;

pharmaceutical product sample – two standard packages or in the quantity required for two tests.

All homology identification documents shall be submitted in English or Russian. Otherwise they shall be attached with attested Georgian translations.

The Agency makes administrative examination of the documents filed by the person concerned ⁶ as well as registers information concerning the pharmaceutical product with the Departmental Registry within 7 business days.

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³ What is meant under the “original instruction” is clarified by the Order No. 325/n of the Minister of Labor, Health and Social Protection of Georgia, dated 13 October 2009.

⁴ Such equivalent documents are determined by the Order No. 344/n of the Minister of Labor, Health and Social Protection of Georgia, dated 23 October 2009.

⁵ Under pharmacopoeia is meant the US Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia and International Pharmacopoeia.

⁶ Georgia unilaterally recognizes quality, efficiency and safety requirements for admission of pharmaceutical products into the relevant markets by an intergovernmental pharmaceutical products regulatory body or a regulatory body of foreign countries and does not make a repeated examination of admitted pharmaceutical products. Notwithstanding the above, the Agency is authorized to verify the documents submitted for registration.
In the end it should be stressed that pharmaceutical products may be proactively registered with the above registry by the Agency based on the information related to certain pharmaceutical product admitted into the relevant market by an intergovernmental pharmaceutical products regulatory body or a regulatory body of foreign countries.

**State Registration through National Regime**

The person concerned for purposes of national regime may be manufacturer of a pharmaceutical product or trade license holder. The person concerned shall submit to the Agency:

- an application;
- document evidencing payment of registration fee; as well as
- registration documents consisting of administrative and scientific and technical parts.

Administrative part of registration documents shall be filed in Georgian whereas scientific and technical part shall be submitted in Georgian, English or Russian.

The Agency makes administrative examination of the submitted documents within 14 days period. In case such documents are in line with the requirements of the law the Agency goes over to making scientific and technical examination to establish standardization, quality, safety as well as therapeutic efficiency of pharmaceutical product.

The Agency makes decision on registration of the pharmaceutical product in the form of an administrative act within 2 months period. It shall as well issue a document evidencing admission of the pharmaceutical product into the Georgian market within 10 days. It should be noted that the administrative act and the above document have the same legal effect.

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7  Holder of pharmaceutical product manufacturing pharmaceutical product itself or through other persons

8  Such fee amounts to 2500 Georgian Lari for innovative pharmaceutical product and to 500 Georgian Lari for generic pharmaceutical product.

9  Scientific and technical part may be filed in electronic form.
If the Agency refuses to register the pharmaceutical product, it shall immediately notify thereof the person concerned in writing same time referring to the ground(s) of such refusal.

In case the person concerned will not be notified of the decision of the Agency on refusal of registration within the terms established by the law for administrative as well as scientific and technical examinations, then the pharmaceutical product shall be deemed as registered and the Agency shall issue a document evidencing admission of the pharmaceutical product.

The Agency shall as well register the pharmaceutical product with the Departmental Registry upon completion of the above procedures.

The registration of pharmaceutical products through national regime is valid for 5 years.

Finally it should be noted that pharmaceutical products for purposes of both recognition and national regimes are admitted to circulation (however import thereof is prohibited) even after the term of their registration is over up to the moment of lapse of their expiration date.
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