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# STREAMLINING REGISTRATION OF IMPORTED PHARMACEUTICALS AND DRUGSTORE PERMITTING PROCESS

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## EXECUTIVE SUMMARY

This document provides recommendations for streamlining registration of imported pharmaceuticals and drugstore permitting procedures. It does not address the drug policy issues involved in a regulatory regime such as pre-marketing assessment and evaluation, post-marketing surveillance, or a pharmaco vigilance system.

These recommendations will simplify the process of registering pharmaceuticals already approved by internationally recognized authorities, reducing transaction costs for both the private sector and government, and increasing operational effectiveness.

## REGULATORY FRAMEWORK

Pharmaceuticals imported to Georgia must be registered and import permits must be issued in some cases.

The Georgian Law on Licenses and Permits, as amended on June 24, 2005, specifies only one type of permit for import and export of pharmaceuticals subject to special control. The list of those pharmaceuticals, which generally consists of narcotics and psychotropic substances, is determined by international regulations and is also approved by Order of the Minister of Labor, Health and Social Affairs. Additional terms for issuing permits for import or export of pharmaceuticals subject to special control are defined by GOG Regulation # 176 of October 14, 2005.

Registration procedures are outlined in the Georgian Law on Drugs and Pharmaceutical Activities, as amended on October 11, 2005. All pharmaceuticals within Georgian territory must be registered, with some exceptions. Unregistered pharmaceuticals can enter the territory of Georgia only:

- for clinical and preclinical trials
- as a sample for state registration
- for individual use
- for use by crews on international flights
- for humanitarian purposes
- as a sample for exhibitions, symposiums, etc., without the right to sell
- for re-export

The current procedures for customs control of pharmaceuticals are defined in the Joint Order of the Minister of Finance and the Minister of Labor, Health and Social Affairs on Rules and Conditions for Customs Registration of Pharmaceuticals. Fees for registration of pharmaceuticals are defined in the Georgian Law on Registration Fees as amended on October 11, 2005.

Sale of pharmaceuticals in drugstores is subject to permit requirements. The Georgian Law on Licenses and Permits, as amended on June 24, 2005, specifies three types of permits for drugstores:

- Permit to organize a Group I Drugstore
- Permit to organize a Group II Drugstore
- Permit to organize a drugstore point, which is a small kiosk usually located within a larger store such as a supermarket.

Additional terms for issuing permits for drugstores as well as permits to import or export pharmaceuticals subject to special control are defined by GOG Regulation # 176 of October 14, 2005.

## CURRENT PROCEDURES FOR REGISTRATION OF PHARMACEUTICALS

Registration of pharmaceuticals in its essence is similar to permitting. It entails approval of a regulatory body, the Georgian Drug Agency and requires more complex procedures than permitting. Requirements differ by drug type, such as new products, generics or herbal remedies, and by registration type, initial registration, re-registration, changing the existing registration. Registration procedures for generics and products other than new drugs are simpler. Procedures for re-registration and changing the existing registration also differ from those of initial registration. The Law on Drugs and Pharmaceutical Activities provides the following procedures for registration of newly developed products.

|   |  |
|---|--|
| <b>Procedure 1:</b> File a new drugs registration application with the Drug Agency.   |  |
| Registration dossier consists of two sections: administrative and technical.<br>The administrative section should include:  |  |
| <ol style="list-style-type: none"> <li>1.1 Cover letter and a list of attachments</li> <li>1.2 A completed Application Form</li> <li>1.3 Power of attorney</li> <li>1.4 Original WHO certificate or document confirming the production of pharmaceutical according to GMP standard or license for production of pharmaceutical issued by the duly authorized agency of the country of production</li> <li>1.5 Packaging of the pharmaceutical with standard marking, which can be in electronic form.</li> <li>1.6 Package insert in Georgian language.</li> </ol>  |  |
| The technical section should include:   |  |
| <ol style="list-style-type: none"> <li>1.7 Proof of registration in the country of production and other countries if any</li> <li>1.8 Chemical composition, indicating all ingredients and their amount in the dose</li> <li>1.9 Specification and methods of analysis for actives substance(s)</li> <li>1.10 Name and address of the producer of the active substance(s)</li> <li>1.11 Specification and methods of analysis for non-active substances</li> <li>1.12 Methods of analysis and specification of pharmaceutical</li> <li>1.13 Scheme of technological processes of production</li> <li>1.14 Samples of the pharmaceutical with corresponding quality certificate</li> <li>1.15 Reference standards with corresponding quality certificate</li> <li>1.16 Data on stability of pharmaceutical</li> <li>1.17 Data from preclinical trials</li> <li>1.18 Data on toxicity trials</li> <li>1.19 Data on teratogenicity, mutagenicity, embryo toxicity, carcinogenicity, allergenicity, etc.</li> <li>1.20 Clinical data on side effects</li> <li>1.21 Report on clinical trials of the pharmaceutical</li> <li>1.22 Summary data on side effects</li> <li>1.23 Experience with clinical use of pharmaceutical</li> </ol> |  |
| <b>Procedure 2.</b>   | Drug Agency conducts an administrative examination of the registration application.  |
| <b>Time Required:</b>   | 14 days  |
| <b>Procedure 4.</b>   | Agency conducts technical examination.<br>Applicant is given 2 months to correct problems with administrative or technical sections discovered during examination. |
| <b>Procedure 5.</b>   | Registration decision is made and administrative act is issued   |
| <b>Time Required:</b>   | 3 months from the time a completed application is submitted.   |
| <b>Procedure 6.</b>   | Registration certificate is issued   |

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| <b>Time Required:</b> 10 days |
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Registration is valid for 5 years. After 5 years the registration must be renewed. Application for re-registration must be filed 2 months prior to the expiration of registration period. The re-registration procedure is described in the table below:

|  |  |
|--|--|
| <b>Procedure 1.</b> File the re-registration application with the Drug Agency  |  |
| Only the administrative section of the application and the following additional documents are required:  |  |
| <ul style="list-style-type: none"><li>- Document confirming the payment of the registration fee</li><li>- Data from last 5 years on side effects of the pharmaceutical</li><li>- Publications and bibliography</li></ul> |  |
| <b>Procedure 5.</b>  | Registration decision is made and administrative act is issued |
| <b>Time Required:</b>  | 2 months   |
| <b>Procedure 6.</b>  | Registration certificate is issued                             |
| <b>Time Required:</b>  | 10 days  |

The Law on Drugs and Pharmaceutical Activities does not outline a clear registration process. There are ambiguities allowing for multiple interpretations concerning the time frames. Regulations do not make it clear whether the clock is stopped when corrections or alterations are requested from the applicant. Nor is it clear when the Drug Agency’s three-month decision making period starts. Does it start when document sufficiency is determined within 14 days after filing the application? Or does it start when the application is complete?

Such ambiguities and time pressures on the Drug Agency to complete the full assessment creates the possibility of government discretion. Time given to the applicants for correction of application dossiers and obtaining additional information sometimes proves insufficient due to the nature and complexity of the requested documentation. The registration process is often viewed as non-transparent and inefficient by importers of pharmaceuticals.

## PROCESS OF REGISTRATION INTERNATIONALLY

In order to register new drug in developing countries, pharmaceutical companies develop a dossier that describes the quality, safety in animals and humans, and efficacy of the product for a specified indication. According to the UK Department for International Development Health Systems Resource Center, a full registration process for a new drug<sup>1</sup> would include:

- Evaluation and assessment of the pharmaceutical quality data, including:
  - verifying that the manufacturers of all components are certified as meeting the appropriate international GMP standards, with inspection of manufacturers;
  - laboratory testing of the product against the proposed specifications for content and impurities, stability data, and packaging; and,
  - evaluation of the labeling to ensure that it complies with specified standards;

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<sup>1</sup> Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries, Suzanne Hill & Kent Johnson, DFID Health Systems Resource Centre

- Evaluation of animal, preclinical, and toxicology studies in relation to acute and chronic toxicity, genetic toxicity, teratogenicity, carcinogenicity and others, including whether the studies have been carried out in accordance with international standards and whether the data and interpretation of the results are valid;
- Evaluation of human clinical trials that have been carried out to define the dose, frequency and duration of treatment that is effective and safe; and,
- Evaluation of the product information document, called the Summary of Product Characteristics in the European Union, including the proposed indication and claims against the available data and the patient information leaflet.

The time taken to complete the assessment of a new chemical varies from country to country and from product to product. If the chemical is well developed, is chemically straightforward, and has trials that indisputably establish efficacy and safety of the product, it is possible to complete a registration review in three months if all the data is available and appropriate. Such cases are very rare. Many countries now have legislated maximum times allowed for review of dossiers. In EU Countries target time-frames are 210 days for major applications, which can be extended by ‘stopping the clock’ to obtain extra information from the sponsor.

Developing country regulators are often under-resourced and lack the high level of scientific expertise needed for the effective assessment of registration dossiers for new chemical entities and generics. It has been argued that it is better for developing countries to rely on the assessments of major regulatory authorities, such as those in the US and Europe, when faced with an application for registration of new chemical entities.<sup>2</sup>

Some of the arguments for basing approval on those of major regulatory authorities are:

- Most developing country regulators do not have the expertise to assess the new chemical entity dossiers.
- New chemical entity dossiers are generally assessed by at least both the US and European authorities and their decisions should be an adequate basis for other countries, given that the data in a dossier are usually the same for every country, although the proposed indication may vary.
- Locally available expertise could be more usefully employed in assessing generic products or problem products in the local market.

## **REGULATION OF DRUGSTORES**

Pharmaceuticals can be sold at three types of stores: Group I and Group II drugstores and drug selling points, which are small kiosks generally located in larger stores.

Group I drugstores provide full drugstore services, including sale of in-store drug preparations, non-prescription drugs, prescription drugs, and drugs subject to special control. This type of drugstore must be at least 190 sq. meters, and employ at least one pharmacist-analyst and one pharmacist-technician.

Group II drugstores can provide any combination of drugstore services, which must be specified at the time of application. Group II drugstores must be at least 40 sq. meters and employ one pharmacist-analyst and, if the drugstore will be preparing certain forms of medications in the store, one pharmacist-technician.

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<sup>2</sup> <http://www.eldis.org/healthsystems/regulation/capacity.htm>

Drug selling points can sell only non-prescription drugs and prescription drugs in tablet or powder form, except for drugs subject to special control. Drug selling points must have at least 8 square meters, and be separated from other areas with a glass partition. Space can not be shared with any other services.

This type of drugstores is mainly located in food stores and supermarkets. Drug selling points were initially intended for mountainous and remote village areas to create incentives for providing limited drugstore services, but this did not prove to be a sufficient incentive to set up a drug selling point. In such areas, a limited amount of certain drugs are provided to patients in local healthcare offices through state support programs. But there is no legal provision that would allow these offices to sell other commonly use  $\phi$  drugs that are not included in the state support programs. In reality, the need for such drugs exists, and there are cases of unauthorized sale of drugs by the health center personnel.

Also limiting sales only to tablets and powder appears to unreasonably limit consumer choice. There is no clear explanation why drug selling points cannot sell ointments, emulsions, suppository, or liquid medicines.

## RECOMMENDATIONS

### **1. Drug Agency shall rely on approvals from recognized competent authorities.**

It is strongly recommended that Georgia's Drug Agency rely on approvals from recognized competent authorities such as, the US Food and Drug Administration (FDA), the UK Medicines Control Agency, European Medicines Evaluation Agency (EMA), Japan's Pharmaceutical and Medical Safety Bureau (PMSB), Switzerland's Swissmedic, etc., as the basis for a local regulatory decision. The recommendation is to limit the registration process to only the administrative section of the application, and proof of registration by the recognized competent authorities.

### **2. Registration procedures for drugs approved by recognized authorities should follow simple administrative procedural rules.**

Set time frames for registration of these drugs according to the requirements of simple administrative procedures provided in the Administrative Code of Georgia. This would involve changing the registration rules so that the 14 days for determining document sufficiency is reduced to 3 days, and the 3 months for making a decision on registration to 20 days. The procedure should also clearly state that the clock is stopped when extra information is requested from the applicant. An additional 10 days for issuing a registration certificate is also unreasonably long. The certificate should be issued simultaneously with issuance of an administrative act.

### **3. Amend the Law on Drugs and Pharmaceutical Activities to correspond with the Law on Licenses and Permits.**

Law on Licenses and Permits has eliminated numerous licenses and permits, including licenses for pharmaceutical warehouses, pharmaceutical quality control laboratories, drugstore branches, etc. Permits for certain types of drugstores, Group I drugstore, Group II drugstore and drug selling points, were introduced instead. These changes need to be reflected in the Law on Drugs and Pharmaceutical Activities.

### **4. Pharmaceuticals intended for transit should not require registration in Georgia.**

The Law on Drugs and Pharmaceutical Activities allows that unregistered pharmaceuticals can enter the territory of Georgia only in certain cases. These cases include re-export but do not include transit. If pharmaceuticals intended for transit are

registered at the destination country, there should not be any registration requirement in Georgia. Removing such registration requirement will also encourage creation of regional pharmaceutical distribution hubs based in Georgia.

**5. Verify from the health policy perspective whether to modify the drug selling point permit for remote village areas.**

Modifying the drug selling point definition for remote village areas so that the local healthcare offices could serve as drug selling points would legalize the existing sale of drugs by the local health office personnel. This would also help satisfy the demand of local village communities.

**6. Verify from the health policy perspective whether to modify the drug selling point definition to allow the sale of drugs regardless their form (liquid or solid).**

The existing limitation, where drug selling points can only sell solid forms of drugs, limits sales for small pharmacies and reduces choice for consumers. No reasonable explanation was found on why drug selling points can not sell commonly used ointments, emulsions, suppository, or liquid medicines.