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Drug Registration Procedure in Russia

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ABSTRACT

Drug Registration is a procedure of expertise of the pharmaceutical product quality, efficacy, and safety by the Regulatory Authority. The emergence of various formats has enabled the manufacturers of the drug to easily gain access to various markets and thus be able to place their products on the market. The choice of Russia as one of the destinations for the market of the Drug products ensures the manufacturer a good market value. Russia is considered one of the strongest and most promising markets for the registration of drugs. The economic value and the Gross Domestic Product of Russia are indicative of the stable drug market it has. Of late generic drugs are holding a major stake in the pharmaceutical market and are gaining more and more confidence in their usage. The majority of medicines in Russia are generic drugs that are considered valuable for the money and affordable. The Russian Pharmaceutical market is divided into four distinct segments, with the largest being the retail market (approximately 60%) having an annual growth of 15%. In Russia Roszdravnadzor, coming under the purview of the Ministry of Health decides to register the product and issues a Registration Certificate. This present study focuses mainly on the registration process involved, the regulations that are applicable for the generics as well as the labeling regulations that are applicable for the Generic Drug products.

INTRODUCTION

The Drug Regulatory Body is the main governing body that controls the following activities regarding the drug registration:

1. Receipt of the application
2. Transfer of the application to the concerned Dept.
3. Review of the Drug Registration Dossier
4. Labeling Review
5. Queries
6. The regulatory decision for the application was filed[12].

Drug Regulatory Body:

In Russia ***Ministry of Health*** is the main governing body carrying out all the activities for the health & well-being of people in the Russian Federation.

Under the purview of the Ministry of Health ***Roszdravnadzor*** (Federal service on surveillance in social development) coordinates the activities of Drug registration, approval, licensing and approval of manufacturing facilities, and renewal of licenses in the Russian Federation.

National center of Pharmaceutical products (FGU) expertise in the office of ***Roszdravnadzor*** carries out all the activities relating to:

- Quality
- Safety
- Efficacy of the drug products.

Legislative acts:

The legislative acts covering the registration aspects of the drugs in Russia are as follows:

1. **Medicines act 1998.**
2. **"Administrative regulations of the Roszdravnadzor on the execution of state function of pharmaceutical products registration" approved by the ministry of health and social development of the Russian Federation.**

All the regulatory bodies are located in ***Moscow***[13].

Ministry of Health

The Ministry of Healthcare ***(Minzdrav)*** is the federal executive body responsible for drafting and implementing government policy and legal regulation in the area of healthcare, mandatory health insurance, the production and distribution of pharmaceuticals for medical use, including disease prevention measures, medical treatment, rehabilitation and appraisals (excluding medical-social and military medical appraisals), pharmaceuticals activities such as ensuring the quality, efficacy, and safety of pharmaceuticals for medical use, the production, and distribution of medical products. The Healthcare Ministry coordinates and oversees the operation of its subordinated services and agencies, including the Federal Supervision Service for Healthcare, the Federal Medical-Biological Agency, federal state institutions, and unitary enterprises; and coordinates the work of the Federal Mandatory Health Insurance Fund[14].

Organizational Structure

Organizational Structure of Federal Ministry of Health of the Russian Federation

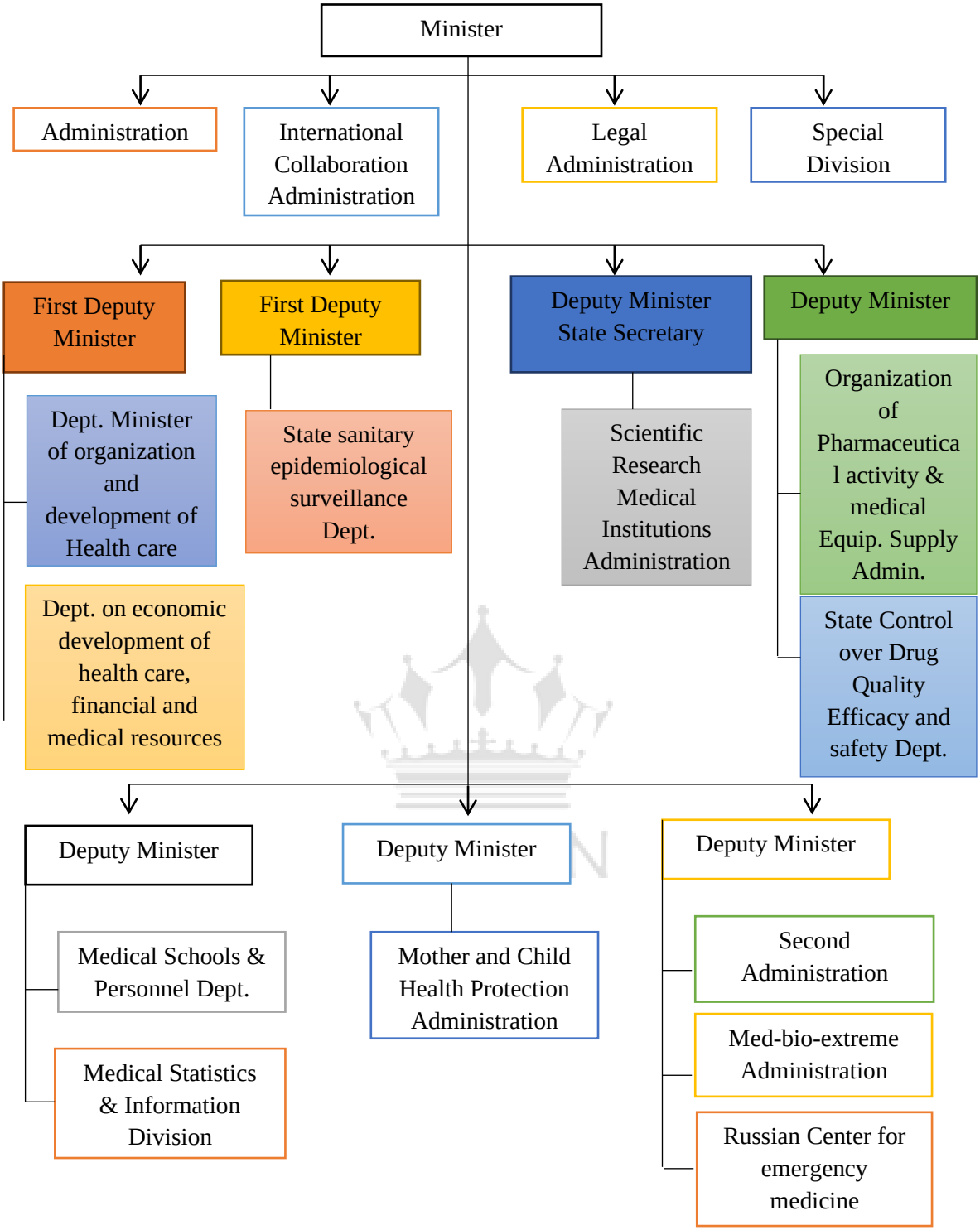

Figure 1: Organizational Structure of the Ministry of Health

The organizational structure of Roszdravnadzor

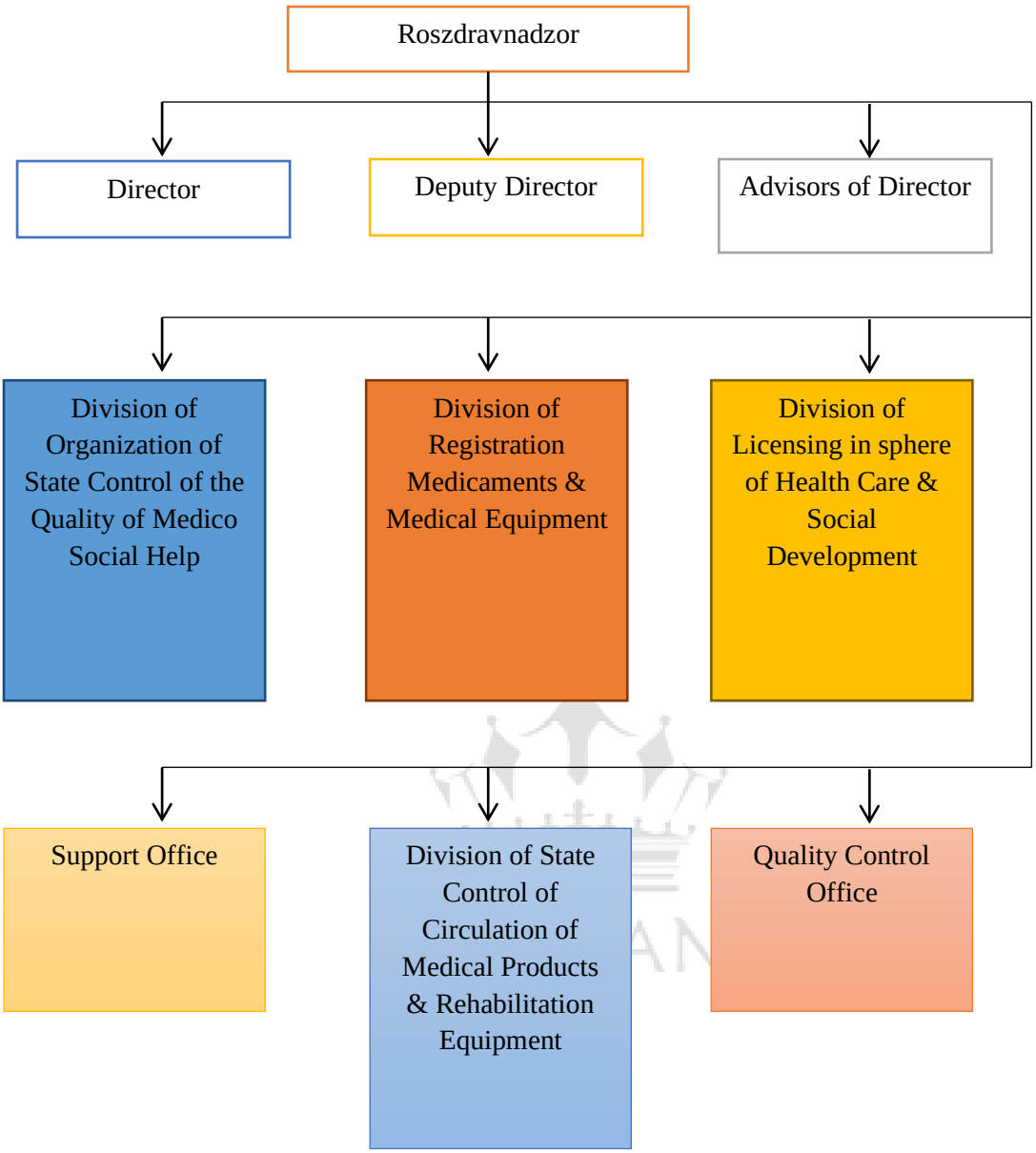

Figure 2: Organizational Structure of Roszdravnadzor

Subordinate Bodies of Roszdravnadzor

1. Federal State Institution "Scientific Center for Expertise of Medical Products.
2. Federal State Institution "Consulting and Methodological Center for Licensing.
3. Federal State Institution "Informational and Methodological Center for Expertise, stocktaking, and Analysis of Circulation of Medical Products.
4. Federal State Institution "All- Russia Scientific Research and Testing Institute of Medical Technique.

5. State Institution "Privolgskiy Circuit Medical Center for Expertise of Quality of Blood Products and Fractionation of Donor Plasma.
6. Federal State Institution "Center for Expertise and Quality Control of Medical Products[15].

Functions of Roszdravnadzor

Roszdravnadzor implements control and surveillance of

- Pharmaceutical activities.
- Compliance with state standards of quality of medical help.
- Compliance with state standards, and technical requirements for medical products.
- Production, quality, efficacy, safety, circulation, and usage of medical products.
- Pre-clinical and clinical trials of medicines.
- Fulfillment of rules in the laboratory and clinical practice
- Compliance with state standards of social services.

Performs inspections of

- Healthcare organizations.
- Pharmaceutical facilities
- Wholesalers of Pharmaceuticals
- Social patronage facilities.
- Other organizations and sole proprietors, work in the sphere of health care and social development.

Organizes

- The expertise in ***quality, Efficacy,*** **and** ***Safety*** of medical products**.**

Issue licenses for

- Medical activities
- Pharmaceutical activities
- Manufacture of medical products except for veterinary drugs and food supplements.
- Manufacture of medical equipment.

Resolutions

- In compliance with the legal requirement of the organization of manufacture of medical products.

Permissions for

- For clinical trials of medical products
- Use of new medical technologies
- Import and export of medical products following the legislation of Russia
- Import of unregistered drugs for use in clinical trials.

Registers

- Medicines and medical devices
- Limit prices on the substantial and vital medicines following the legislation of Russia.

Administrates

- State registry of medicines
- State registry of prices on the substantial and vital medicines
- List of healthcare institutions, entitled to conduct clinical trials.

Possesses Right to

- Free access to pharmaceutical manufacturing facilities, to collect samples of manufactured medicines by the legislation of Russia.
- Prohibit the manufacture and sale of Pharmaceuticals in cases determined by the rules of manufacture and control of the quality of medicaments following the order established by the legislation of Russia.
- Apply the restricting, preventing, and prophylactic measures established by the legislation of the Russian Federation for the banning and/ or liquidation of the consequences of the violation of the law requirements in the sphere of public health and social development.

Pharmacovigilance

- Revealing and monitoring of adverse reactions at the usage of
  - Medical devices.
  - Medicines

- Medicines for use in the clinical trials[16]

Drug Registration Procedure

Drug Registration:

- Drug registration is defined as the procedure of review of pharmaceutical product quality, safety, and efficacy by the State Regulatory Authority.
- In Russia, for a product to be marketed and sold the product must be registered first. After the registration, the product is entitled to a registration certificate by the Roszdravnadzor, and the product is introduced into the database of registered products in Russian Federation.

In Russia, there are 2 strictly divided categories.

1. **Pharmaceutical products.**
2. **Food supplements and cosmetics**

For a product to be registered it must be associated with any of these categories. The registration review for the above products differs to a greater extent from one another and the different regulatory pathway is applicable. Pharmaceutical products require much documentation, and much expert review when compared to food supplements and cosmetics, which require less expert review.

Applications for Drug Registration are forwarded to the "National Center of Pharmaceutical Products expertise" (FGU) for review.

The registration procedure is organized in such a way that there exists a flow of communication between regulatory affairs personnel and experts reviewing the application for the dossier.

Registration procedure for foreign applicants:

The registration procedure is the same for foreign manufacturers and local manufacturers. Differences appear only in the cost and documents. The most important prerequisite for a foreign manufacturer is that he should be having a valid GMP certificate for the product to be registered.

The product is not necessary to be registered in the country of origin or another country.

Applicant Credentials:

1. Marketing authorization holder or its representation in Russia
2. Physical person.
3. Russian Juridical Company (Third Party).

- If any firm is representing the interest of the ***Marketing Authorization Holder***, the representation must be legalized by a ***Power Of Attorney.***

Documents to be legalized:

1. Certificate of Analysis.
2. GMP- Certificate.
3. Manufacturing license.
4. CoP (Certificate of Pharmaceutical Product).

If the documents are state official documents issued by a state member of the Hauge Convention, such documents must be apostilled. If not the documents should be endorsed by the Russian Embassy.

Drug Registration Procedure:

The drug Registration procedure for drugs is divided into 3 stages. Of all the stages, II nd stage is considered the most difficult and longest stage in drug registration.

Stage I:

- In ***stage I*** the applicant prepares the dossier and compiles all the necessary documentation so that the document consists logical flow of the information. In this stage, it is compulsory to collect all the necessary documents and translate the documents into the Russian language and compile the dossier.
- All the documents to be submitted should be in the **Russian** Language.
- After the compilation of the dossier, the applicant submits the dossier translated completely into the Russian language, to the ***National Center of Pharmaceutical Products Expertise (FGU)***.

Stage II:

- In this stage, the FGU reviews the submitted dossier content to assure the Quality, Safety, and Efficacy of the pharmaceutical product and to check the conformance to the standards laid out by the **Roszdravnadzor**.
- In the FGU the review is done in the following way

Institute of products quality control: carries out the expert review in terms of quality adherence and quality control.

Institute of Preclinical and clinical: carry out the expert review in terms of efficacy and safety matters.

Stage III:

- In this stage the expert review is completed and the documents are forwarded to the main office of Roszdravnadzor to issue the regulatory decision.
- Once the necessary documents are furnished and submitted to the office of Roszdravnadzor, after the payment of the necessary fee the application is directed to the experts appointed by Institutes of Products Quality Control and Institutes of preclinical and clinical experts.
- If any further information is required, it is the duty of the applicant and his representative to furnish the information required, and carry out the necessary formalities, so that the approval is given without much waste of time and loss to the manufacturer.
- The regulatory decision is issued based on the unbiased review carried out by the expert committee and a decision is issued if there are no deficiencies found in the submission made.
- In the institute of products the verification of finished products specification is done as per the Russian Normative Documents, also verification is done by laboratory control.
- In the Institutes of preclinical and clinical experts, the review is done for New Drug Applications. In case if there is the necessity of preclinical or clinical tests the product is directed to the specialized research institute.
- Innovator drug and generic drugs must pass all stages of registration. However the review of new drugs is done extensively and they must pass all the registration procedures, while generic drug products are exempted from some of them.

For *Generic Drug Products* there is no need to carry out the time-consuming and pocket-burning, clinical trials. Only *Bioequivalence studies* should be carried out and it need not be carried out in *Russia*. Whereas for *New Drugs* there is need to carry out the clinical trials and the clinical trials must be conducted in Russia only, particularly in the *Russian Population*.

During the registration process, all the products must pass laboratory control as per the approved ***Normative Document***.

Normative document:

- The submission of a document according to which the quality of a drug will be controlled is required for the registration of a drug product or a drug substance.
- This document is a regulatory document (normative document) for products and substances manufactured abroad and in Russia.
- The documents are similar both in purposes and in contents.

The normative document consists of:

- specification, where quality parameters of a drug, evaluation of every parameter, and limits are determined;
- description of composition (active ingredient and excipients) and appearance of the product;
- description of identification, mean weight, pH, disintegration, dissolution, content uniformity methods;
- microbiological quality, assay, and impurities methods;
- description of the container closure system, labeling, storage conditions, and shelf-life.

Import of the samples to carry out laboratory control tests:

To import samples in Russia is important and the standards for laboratory control it is necessary to receive special import permission from Roszdravnadzor. The time duration to import these samples is 1-2 months depending on the satisfaction of the custom dept., specifications.

The full analysis of the pharmaceutical product is done during the stage of registration and it is done on the first three batches imported into the Russian market for selling. The time taken

to carry out laboratory control tests is 4 months and additional two months are required to import necessary standards. The laboratory control tests can be done only when sufficient standards are available in the laboratory.

License to carry out the pharmaceutical activity in Russia

To obtain a license for pharmaceutical activity license applicant sends or submits to the Federal Service on Surveillance in Healthcare and Social Development the following documents (in Roszdravnadzor control subjects of the Russian Federation):

An application for a license for pharmaceutical activities, which shall include:

- Full and (if applicable) the abbreviated name, including the company name and legal form of a legal entity, its location, the address of the place of the pharmaceutical activities, which the applicant intends to carry out the state registration number of the record to establish a company and the data of the document confirming the entry of data on a legal entity in the state register of legal entities for a legal entity.
- The name and (if applicable) first name of an individual entrepreneur,
  - his place of residence,
  - the address of the place of the pharmaceutical activities, which the applicant intends to carry out,
  - the data document proving his identity,
  - the main state registration number of the record of the state registration of an individual entrepreneur
  - data document confirming the fact of information about an individual businessman in the state register of individual entrepreneurs - for a sole proprietor.
- A taxpayer identification number and document data about the production of the license applicant for tax registration.
- Licensed activity that the license applicant intends to carry out.
- Copies of the constituent documents - for a legal entity.
- A document confirming payment of the state fee for consideration by the licensing body of the application for a license.
- copies of documents confirming the right of ownership or other legitimate reason to use the premises and equipment for the pharmaceutical activities.

- copies issued in the established order of the sanitary-epidemiological certificate of conformity to sanitary facilities;
- copies of the higher or secondary pharmaceutical education, the work experience in the relevant specialty, and specialist certificates (degrees, certificates, etc.).
- All documents for the licensing of pharmaceutical activity are served in Russian or have a certified translation into Russian.

Registration documents required:

Registration documents consist of a set of documents that contain the complete data set of information about drugs that aid in the approval process of Drug registration.

The registration dossier consists of 6 parts which are as follows:

1. **Administrative documents.**
2. **Description of pharmaceutical properties (Drug Substance).**
3. **Data about the manufacturing of the pharmaceutical product.**
4. **Data about quality control of the finished product.**
5. **Data about preclinical pharmacological and toxicological studies of a pharmaceutical product.**
6. **Data about clinical studies of a pharmaceutical product.**

Administrative documents:

The official document(s) confirming the right to produce the drug, the presence of the necessary manufacturing environment, and its accordance with the local or international standards as well as the marketing information (the Manufacturer's national market or the market of any other country). The documents must be issued by correspondent authorized agencies and attested by legislation prescriptions (notarized and legalized (if necessary))[17].

These official documents can be the following documents:

- CPP (certificate of pharmaceuticals product) prepared following WHO's recommendations or Registration Certificate;
- Free Sale Certificate and GMP;
- Production license (for local Russian Manufacturers) and Registration Certificate;
- Other equivalent documents.

The mentioned above documents have to contain information about all organizations involved in the drug production process at all stages (patent medicine production, packing, output quality control, and other intermediate production stages).

Legally attested documents (agreements, etc.), containing information about all participants in the drug production process;

Power of attorney for the activity dealing with the drug quality, efficiency and safety experts' examinations conducted, issued to the person representing the Applicant.

Table 1: Administrative Documents

Sl. No	Administrative documents
1.	Power of Attorney issued by Registration Certificate Holder of the product in Russia to the company which will represent the interests in the questions of registration *(legalized by Russian Embassy or apostilled)* *(draft is provided upon a request)*
2.	Original payment order of state tax payment in Russian rubles
3.	Patent for registered brand name *(in case of existence)*
4.	Summary of Product Characteristics (SPC) or instruction for administration for specialists
5.	Certificate of Pharmaceutical Product *(legalized by the Russian Embassy or apostilled)*
6.	Copies of Registration Certificates (Marketing Authorizations) from other countries in case the product is registered in other countries (*in case of existence*)
7.	Colored mock-ups of primary and secondary packaging (with Pantone codes)

Table 2: Data about API (active pharmaceutical ingredient) used for manufacturing of the finished pharmaceutical product.

Sl. No	Data About API
1.	***GMP certificate of API manufacturer*** (legalized by the Russian Embassy or apostilled) – in the document obligatory must be mentioned the following information: • INN or chemical name of API, • Name • Address of API manufacturer
2.	***Certificate of analysis of API*** issued by API manufacturer (for recent batch valid at least 6 months) Original or a copy with signature and stamp of the finished product manufacturer's authorized person).
3.	Certificate of analysis of API issued by the manufacturer of the finished product (for the same batch as CoA provided in point 9) Original or a copy with signature and stamp of the finished product manufacturer's authorized person).
4.	Certificate of suitability for API issued by EDQM (in case of existence).
5.	• Nomenclature (INN or chemical IUPAC name), • Classification, • Structural formula, • Molecular formula, • Molecular weight, • General physicochemical • Microbiological properties of API, • impurities of API and their description.
6.	Specification and analytical methods for quality control of API (+ Monograph from EP, USP, BP) or Russian Normative Document (ND) for API registered in the Russian Federation, Registration Certificate of API.
7.	Data about validation of analytical procedures of API: summary (it is not required in case API has a monograph in EP, USP, BP or Russian Ph.)

8.	Stability data for API for 3 batches: • Justification of the shelf-life, • Storage conditions, • Type of stability study *(could be provided as a table, report or short review)*
9.	API manufacturing process scheme: Should be provided as a flow chart with the reflection of the consequence of all manufacturing stages (and steps) and their obligatory enumeration. Details to be present in the scheme: • Raw material used • Intermediate products and • Product yield.
10.	Description of the API manufacturing process: Described consecutively by stages (and steps) following the scheme provided in p.16. Also, intermediate control should be provided.
11.	Material balance: • Batch size (including product yield); • Quantity of starting material used for manufacturing of one API batch and/or all chemical reactions (main and auxiliary) on every stage with a molecular weight of substances; • Explanation of the principal of API batch number generation.

Table 3: Data about the manufacturing of the finished pharmaceutical product

Sl. No	Date to be present.
1.	Name and address (juridical and production site) of the finished product manufacturer at all stages: • Finished product, • Primary packaging, • Secondary packaging, • Batch release
2.	***GMP-certificate*** Good Manufacturing Practice of the finished product manufacturer legalized by the Russian Embassy or apostilled. *For a foreign manufacturer/ applicant the presence of a GMP certificate from the country of origin is must and should.*
3.	Manufacturing License of the finished product manufacturer *(Legalized by Russian Embassy or apostilled).*
4.	***Finished product manufacturing process scheme:*** Should be provided as a flow chart with the reflection of consequences of all manufacturing stages (and steps) and there • Obligatory enumeration. • Intermediate control on every stage should be shown.
5.	***Description of the finished product manufacturing process with intermediate control:*** It has to be described consecutively by stages (and steps) following the previous step.
6.	***Material balance:*** • Quantity of active and auxiliary substances used for manufacturing of one batch of the finished product; • One batch size is expressed in quantity of finished product packs received; • Explanation of the principle of the finished product batch number generation.
7.	Finished product manufacturing process validation
8.	***Pharmaceutical development:***

	• Formulation development; • Manufacturing process development

Table 4: Data about quality control of finished pharmaceutical products.

Sl. No	Documents
1.	***The full composition of finished product per one dosage unit:*** • Including composition of capsule shell, • Coat of tablet, printing ink used for printing of text on the capsule shell, etc
2.	Release and shelf-life specification and analytical procedures for quality control of the finished pharmaceutical product.
3.	Validation of analytical procedures with information about the number of batches (quantity of samples) used for validation
4.	Certificate of analysis for 3 batches of the finished product (for recent batches valid at least 6 months) (original or a copy with signature and stamp of the finished product manufacturer's authorized person).
5.	Certificate of analysis of excipients (for recent batch valid at least 6 months) (original or a copy with signature and stamp of the finished product manufacturer's authorized person).
6.	Certificate of analysis of reference standards used for quality control of the finished product (original or a copy with signature and stamp of the finished product manufacturer's authorized person)
7.	Characterization of impurities of a finished pharmaceutical product.
8.	Description of container closure system (primary and secondary packaging)
9.	Justification of container closure system selection.
10.	Certificate of analysis of primary and secondary packaging. • Lay-out or schematic drawing of the package could be provided in the case of necessity.
11.	***Packing of the product for the Russian market:*** • Quantity of the product in primary packaging and secondary packaging

	(for ex. X tablets in Alu/PVC/PVDC blister; XX blisters in carton)
12.	***Stability data:*** • Stability data tables for 3 batches under normal (and/or accelerated) conditions for the whole shelf-life, performed on all quality tests included in the specification for the finished product. • stability summary with a conclusion about received stability data for all types of primary packaging.
13.	Information about storage conditions and shelf-life of the finished product

Table 5: Data about Non-Clinical Pharmacological and toxicological studies of finished Pharmaceutical Product.

Sl. No	Documents
1.	Report about results of the own preclinical study which contains description, results, and statistical analysis of the results (copy with signature and stamp of the authorized person): • Non-clinical Pharmacology – major pharmacodynamics studies; • Non-clinical Pharmacokinetics – major pharmacokinetics studies; absorption; distribution; metabolism; excretion; drug interaction; • Non-clinical Toxicology – single-dose toxicity (acute), repeat-dose toxicity (subchronic and chronic), genotoxicity, carcinogenicity, reproductive and developmental toxicity, local tolerance, and other studies; • General conclusions of the study; • Literature references.
2.	**Literature overview of preclinical data:** • Non-clinical Pharmacology – results of studies that confirm the pharmacological activity of pharmaceutical products; • Non-clinical Pharmacokinetics – absorption; distribution; metabolism; excretion; pharmacokinetic Drug Interaction; • Non-clinical Toxicology – single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity, reproductive and developmental toxicity, local tolerance, and other studies.

Data about studies:

- Reports of bioequivalence conducted outside the Russian Federation (BE study reports.
- **Literature clinical efficacy and safety overview.**

Documents necessary for receiving official permission for clinical trial beginning in Russian Federation (applicable for New Drugs):

- Draft of the protocol for a clinical trial in the Russian Federation
- Researcher brochure
- The information leaflet for the patient
- Information about payments and compensations for patients-participants in the clinical trial
- Data about researcher's experience as a specialist and their experience in clinical trial conduction
- Copies of the contracts for life and health insurance of the patients

Timelines for registration:

The timelines for registration of drug product varies from type of the product and based on its application and differs from that of Medical Devices. The duration of the registration process varies, depending upon the regulatory specialist's organization and efficacy.

The need to conduct additional studies or implement quality control systems or sometimes the need for additional information delays the application approval process[18].

Table 6: Timelines for registration of Drugs

Stages	***Time Required***
Stage 1	2 Months
Stage II	12 Months
Stage III	4 Months
Total Time for Registration	18 months

Table 7: Registration fees

Name of procedure	*Cost in Dollars*	*Cost in Euros*
Examination of Documents	22,000-30,000	16,000-25,000
Laboratory quality expertise	2,000-6000	1,400-4000
Total	24-36,000	17,400-29,000

The applicant has to pay the whole sum of money at the beginning of the registration process. The registration review process will not begin unless the applicant pays the raised invoice for the fees.

The cost of laboratory quality review depends upon the number of dosages and the analytical method adopted by the expert review board to analyze the given sample of drug.

Language Requirements:

The language accepted for the submission of the dossier file must be the Russian language. Any other document/ supporting documents if any present, which accompany the dossier must also be in the Russian language.

For the documents present in a language other than Russian language, translation into Russian language is a must and should be done taking the help of expert language translators. The meaning of the contents should not change after the translation of the documents.

Post Registration variations:

Once after reviewing the dossier by the regulatory authorities in Russia, the out of the review would be either approval or denial of the registration certificate. Along with the registration certificate, the applicant gets the following documents.

1. Normative documents
2. Instruction for administration.
3. Colored design of the packaging.

All the above documents are signed by the representative of ***Roszdravnadzor.***

There are two types of variation post-approval. They are as follows:

- Variation type I
- Variation type II.

Table 8: Types of Variations

Type	Review	Examples
Variation type I	**Does not require review by quality, safety and efficacy expert**	**Change in the name of the manufacturer, change of marketing authorization holder, change in the package design**
Variation type II	**Requires review by quality, efficacy and safety expert**	**Change in the manufacturing site. Change in quality or quantity composition Change of instruction for administration**

Table 9: Approval Times

Type of variation	Time Required
Variation type I	**2-3 Months.**
Variation type II	**6-12 Months.**

SUMMARY:

The pharmaceutical growth in this sector is promising, with many companies aiming to set up their facilities in this region. Today the affordability of medicines limits people from the base class the accessibility to the quality medicines and they are deprived of the quality medicines.

Generic drugs help people coming over this gap and grant access to them quality medicines that can be of immense help.

Generics in this region conquer about 20% of the pharmaceutical market and by the year 2016 they are expected to conquer 50% share of the pharmaceutical market in this region this serves as a bottom line for the pharmaceutical growth in this sector and this, in turn, is the main contributing factor for choosing the market. The number of generic drug approvals in this region has raised considerably and has gained momentum.

Russian federation is marked by continuous economic growth and the evidence of the growth is reflected in the market's GDP (Gross Domestic Product). The work also covers the miscellaneous issues such as drug trafficking, etc. that are a matter of concern from manufacturers' as well as the government's point of view.

The present work covers the timelines associated with the approval of the drug and vividly gives a picture of the working of the Roszdravnadzor and clearly explains the scenario of the pharmaceutical market in the Russian federation.

CONCLUSION:

The choice of the market always remains a point of concern for the manufacturer as the fate of the organization depends on the adaptability of the product in that market which results in profit.

The present study helps in the following way:

- **Assess** the market value by using the market present scenario and forecast.
- **Monitor** the progress of the market by checking the latest developments.
- **Understand** the growth-promoting factors and drivers of the market and select the best factor from the lot.
- **Evaluate** the environment for the generic drugs taking into consideration the acceptability and affordability of medicines.
- **Restructuring** the business strategies to suit the market.

Russia is expected to be among the top five global markets in terms of the value in next five years. Though the process of registration is intimidating, the process does not appear to be so

complex when compared to the other developing countries and would surely attract foreign manufacturers.

Today one can see Russia at the edge of being the pharmaceutical hub in the years to come. Russia today would certainly take a different face which one can never imagine. As the nation goes stronger and stronger the Pharmaceutical industry in this region also follows the same pattern and may outstrip the other regulated markets in the years to come.

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