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Overview of Veterinary Medicines Regulatory Environment in the Russian Federation

Abstract:
Veterinary medicine is defined as the sphere of science and practice aimed at preventing and treating animal diseases, manufacturing valuable and veterinary/ sanitary safe animal products and protecting the population from those diseases that are common for humans and animals. A classical pharmaceutical for the treatment of a physiological disease in animals will be considered to be a veterinary medicinal product by most regulatory authorities around the world and will often be assessed in a way very similar to pharmaceutical products for humans. The pharmaceutical industry for humans and animals is one of the most important components of the strategy of national and political security of any state. Moreover, it is also one of the most profitable and rapidly developing segments. Accordingly, the pharmaceutical markets of both developed and developing countries are regulated by a significant number of laws, regulations, guidelines and orders, guaranteeing the national public quality, efficiency and safety of medicinal products. Registration is a key process in the system of finished pharmaceutical products circulation. The registration and import of veterinary drug plays an important role in order to market the product. In the Russian Federation, the veterinary medicine follows the registration pattern: "one law, two authorities" and is regulated by the national Ministry of Agriculture (separately from human medicine). The aim of this article is to provide an overview of veterinary pharmaceutical market and regulation involved for drug registration and import in Russia.

Keywords: Phytosanitary Surveillance, Bioequivalence study, Immunotoxicity

Introduction

Russia – officially the Russian Federation – is a country in Eurasia. At 17,125,200 square kilometres (6,612,100 square miles), Russia is the largest country in the world by area, covering more than one-eighth of Earth's inhabited land area, and the ninth most populous, with a population of about 144.5 million as of 2018. About 77% of the population live in the western, European part of the country. Russia's capital, Moscow, is the largest metropolitan area in Europe proper, and one of the largest cities in the world; other major cities include Saint Petersburg, Novosibirsk, Yekaterinburg and Nizhny Novgorod. Extending across the entirety of Northern Asia and much of Eastern Europe, Russia spans eleven time zones and incorporates a wide range of environments and landforms.[1]

- Capital: Moscow
- Population: 143,912,402 (country comparison to the world: 9)
- GDP – per capita (PPP): 10,608 USD
- Official language – Russian
- Surface area: 17,098,250 km^2

Economy of Russia

Russia has an upper-middle income mixed and transitional economy with state ownership in strategic areas of the economy. Market reforms in the 1990s privatised much of Russian industry and agriculture, with notable exceptions to this privatisation occurring in the energy and defence-related sectors. Russia contains over 30 per cent of the world's natural resources. The World Bank estimates the total value of Russia's natural resources at $75 trillion US dollars. Russia relies on energy revenues to drive most of its growth. Russia has an abundance of oil, natural gas and precious metals, which make up a major share of Russia's exports. Russia is considered an "energy superpower". It has the world's largest proven natural gas reserves and is the largest exporter of natural gas. It is also the second-largest exporter of petroleum.

Russia has a large and sophisticated arms industry, capable of designing and manufacturing high-tech military equipment, including a fifth-generation fighter jet, nuclear-powered submarines, firearms, and short-range/long-range ballistic missiles. Top military exports from Russia include combat aircraft, air defence systems, ships and submarines.[2]

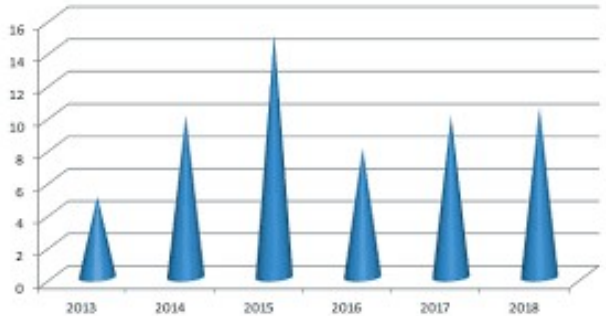
Russia's economic freedom score is 58.9, making its economy the 98th freest in the 2019 Index. Its overall score has increased by 0.7 points, with higher scores for monetary freedom and property rights outpacing declines in judicial effectiveness and trade freedom. Russia is ranked 41st among 44 countries in the Europe region, and its overall score is below the regional and world averages.

Climatic Condition:

The climate of Russia can be described as a highly continental-influenced climate. The enormous size of the country and the remoteness of many areas from the sea result in the dominance of the continental climate with warm to hot dry summers and (very) cold winters, with temperatures of -30°C and lower and sometimes heavy snowfall. It is prevalent in European and Asian Russia except for the tundra and the extreme southeast, where sometimes very strong easterly winds called Buran can occur, bringing freezing cold temperatures and snowstorms. Precipitation varies from region to region; the Western parts of Russia have the most rain (up to 750mm), while the southern and southeastern areas in the Russian Steppes are the driest with an annual average below 200mm. Mountains in the south obstructing the flow of cold air masses from the Arctic Ocean and the plain of the south and north makes the country open to Pacific and Atlantic influences.[3,4] Pharmaceutical products should be proven to be stable at the following conditions: 25°C / 60% r.h., i.e. climatic zone II stability testing.[5]

Koppean climate types of Russia[3]

Pharmaceutical Market
Over the last two decades, Russia's pharma market sat outside of the world's 10 largest pharma markets, but this may change in the coming years. It is set to be worth $36.61 billion by 2021. This represents an annual compound growth of 13%, which should see it firmly placed within the top 10 largest markets in the world. Russia's domestic drug market is predominantly made of generics, which amounts to around 70% of its pharmaceutical makeup. The Russian Ministry of Trade has also issued a state programme to improve domestic healthcare in Russia in general. At the moment, the domestic share of Russia's pharmaceutical products makes up 27%. The government aims to increase domestic share to 50% by 2020.[6]



Pharmaceutical growth rate in Russia[7]

Veterinary medicine:
Veterinary medicine is the branch of medicine that deals with the prevention, diagnosis and treatment of disease, disorder and injury in non-human animals. The scope of veterinary medicine is wide, covering all animal species, both domesticated and wild, with a wide range of conditions which can affect different species.[8]

Veterinary medicine has made many important contributions to animal and human health. Included are dramatic reductions in animal sources of human exposure to tuberculosis and brucellosis. Safe and effective vaccines have been developed for prevention of many companion (pet) animal diseases – e.g., canine distemper and feline distemper (panleukopenia). The vaccine developed for control of Marek's disease in chickens was the first anti-cancer vaccine.[9]

Veterinary medicine is widely practised, both with and without professional supervision. Professional care is most often led by a veterinary physician (also known as a vet, veterinary surgeon or veterinarian), but also by paraveterinary workers such as veterinary nurses or technicians. This can be augmented by other paraprofessionals with specific specialisms such as animal physiotherapy or dentistry, and species-relevant roles, such as farriers.

Veterinary science helps human health through the monitoring and control of zoonotic disease (infectious disease transmitted from non-human animals to humans), food safety, and indirectly through human applications from basic medical research. They also help to maintain food supply through livestock health monitoring and treatment, and mental health by keeping pets healthy and long-living. Veterinary scientists often collaborate with epidemiologists, and other health or natural scientists, depending on type of work. Ethically, veterinarians are usually obliged to look after animal welfare.[8]

Regulatory System:
In Russia, two different authorities are involved in the evaluation and registration of VMPs, namely the Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor) and the Federal State Institution "Russian State Centre of Quality and Standardization of Animal Drugs and Feeds" (VGNKI). The latter is a subordinated institute of Rosselkhoznadzor.

Rosselkhoznadzor examines, approves, and registers veterinary medicines and pesticides for utilisation in Russia. It regulates product registration procedures and the use of officially registered pesticides.

Federal Service for Veterinary and Phytosanitary Surveillance is the federal organ of executive power, carrying out functions on control and supervision in the field of veterinary science. It establishes and lifts phytosanitary quarantine zones, controls the use of pesticides and agrochemicals, maintains soil fertility, is responsible for selection achievements, protection, reproduction and use of objects of the animal world (hunting resources) and aquatic biological resources, and it also carries out functions on protecting the population from animal infectious diseases. The Federal Service for Veterinary and Phytosanitary Surveillance submits to the Ministry of Agriculture of the Russian Federation.

The activity of the Federal Service for Veterinary and Phytosanitary Surveillance is guided by the Constitution of the Russian Federation, federal constitutional laws, federal laws, acts of the President of the Russian Federation and Government of the Russian Federation, international agreements of the Russian Federation, normative legal acts of Ministry of Agriculture of the Russian Federation, and also by the present Act.

The Federal Service for Veterinary and Phytosanitary Surveillance performs its functions directly and through regional bodies cooperating with other federal executive authorities, with the executive organs of the Russian Federation subjects, local self-government institutions, public associations and other organisations.[10]

FSFI VGNKI is a federal governmental agency, which embodies public policy in the field of animal drugs and feed quality assurance and animal products safety and organises the standardisation system in the territory of the Russian Federation. FSFI VGNKI is a reference scientific and methodological centre of the Federal Service for Veterinary and Phytosanitary Surveillance, as well as its territorial affiliates and subordinate bodies.

FSFI VGNKI holds the leading position within the system of federal governmental agencies, which submit directly to the Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadsor) of the Ministry of Agriculture of the Russian Federation. Being the largest European centre for certification of veterinary drugs, feed and feed additives, FSFI VGNKI at the same time represents the largest scientific, methodological and expert centre, which aims to achieve the goals set forth in the Food Security Doctrine.

FSFI VGNKI is the official centre of the World Organization for Animal Health (OIE) on food safety, diagnostics and control on animal diseases in Eastern Europe, Central Asia and the Transcaucasia. The Institute is authorised by the Federal Agency on Technical Regulating and Metrology of the Russian Federation as a

certification body and testing centre for veterinary drugs and feed. [11]

New VMPs:
The content of applications is formally identical for all medicines, according to Federal Law N 61-FZ. Law 241-FZ emphasises the status of reference drugs for veterinary use, clarifying that such drugs must go through pre-clinical and clinical trials in accordance with the requirements established for veterinary drugs. In general, a number of provisions of law are made more detailed by Law 241-FZ, specifically regarding pharmaceuticals for veterinary use.

In addition to this, Law 241-FZ clarifies a number of provisions regarding the powers and interaction of government agencies, including for setting prices on so-called essential (vital) drugs. In order to get expedited expert review of drugs, the order of applications for state registration is defined as under one international non-proprietary name of the drug or drug grouping name.[12]

In addition, subordinate acts regulate the registration process.

Namely, these acts are:

- Ministerial Order N 1413n of 23-Nov-2011: on Approval of the Guideline on the Format and Content of the Registration Dossier of a Medicinal Product
- Ministerial Order N 409n of 12-Jul-2017: On approval of the procedure for the formation of a registration dossier for medical drugs and requirements for documents in its composition, requirements for the amount of information provided as a part of the registration dossier, for the certain types of medical drugs and the procedure for submission of documents that compose the registration dossier for medical drugs for the purpose of its state registration.
- Ministerial Order N 760n of 26-Aug-2010: on the Adoption of an Application Form for a Variation to a Registration Dossier of a Registered Medicinal Product.
- Ministerial Order N 98 18-Mar-2016 on approval of administrative regulations of Federal Service for Veterinary and Phytosanitary Surveillance on provision of the state service in licensing of activities for production of medicines for veterinary application.
- Ministerial Order N 82 1-Mar-2017 on approval of administrative regulations of the Federal Service of the Russian Federation on veterinary and phytosanitary supervision on provision of the state service in issue of the conclusion about compliance of the producer of medicines for veterinary application to requirements of rules of proper production practice.
- Ministerial Order N 366 26-Jul-2017 on approval of administrative regulations of Federal Service for Veterinary and Phytosanitary Surveillance on provision of the state service in state registration of the gene engineering modified organisms used for production of forages and feed additives for animal, the gene engineering modified organisms used for production of medicines for veterinary application, and also forages and feed additives for the animals received using the gene engineering modified organisms or containing such organisms.
- Ministerial Order N 20n 19-Jan-2018 on approval of administrative regulations of the Ministry of Health of the Russian Federation on provision of the state service in issue of permission to performing clinical trial of medicine for medical application.
- Federal Law N 3-FZ of 8-Jan-1998: on Narcotics and Psychotropic Substances, as amended.

All documents and data should be submitted in Russian, or have a certified translation into Russian. The format and structure of the dossier for registration process doesn't follow the VICH format, since the country has its own requirements. In addition, clinical studies performed in Russia are needed. The Federal Law N 61-FZ introduced new requirements for local clinical data in support of all new applications, including generics, new indications and line extensions (human and veterinary). There were no agreements on recognition of clinical data signed between Russian and other national authorities.

Generic VMPs:
In the Federal Law N 61-FZ, "reproduced medicinal products" (generic products) are not subject to an abridged registration procedure. As mentioned above, the application content is the same for all medicines, including generics. However, the documentation on pre-clinical, toxicological and clinical tests of generics differs from that of original medicines.

However, generics are reviewed according to an accelerated procedure. In detail, expedited expert assessment does follow a procedure according to the Federal Law N 61-FZ, art. 26.

Hence clinical studies and findings of a bioequivalence study for a VMP are examined within sixty working days. Bioequivalence studies should be performed in compliance with the regulations approved by an authorised federal executive power body (Federal Law N 61-FZ, art. 12). As a rule, data obtained from clinical trials of medicinal products which have been already published, as well as documents containing results on bioequivalence studies or therapeutic equivalence, should be submitted. An accelerated procedure is not applicable for biological products and products registered in Russia for the first time.

Import Requirements:
Legislation:

- Federal Law N 61-FZ of 12-Apr-2010 on the Circulation of Medicines, as amended
- Basic principles concerning the import of medicines
- Decree of the Government of the Decree N 771 of 29-Sep-2010 on the Procedure of Import of Medicines for Medical Use into the Russian Federation
- Requirements for the content of import applications to various authorities.

For the registration of imported VMPs into the Russian Federation, the NCA Rosselkhoznadzor requires a Certificate of Pharmaceutical Product (CPP). A CPP is also required for changes in chemistry, manufacturing and in the control part of the documentation (CMC) of the product (i.e. change of manufacturing site, of pharmaceutical formulation / composition). In case a CPP is not available, a GMP certificate, a free sales certificate (FSC) and a manufacturing licence can be submitted.

Recent Changes in Legislation:
A TOPRA review about Russian regulatory legislation in 2011 [13], states that the regulatory environment has changed dramatically since Russia's new federal law "on circulation of medicinal products" came into force in April 2010. In general, the introduction of this law "brought a wide range of changes affecting data requirements and procedures for clinical trial applications and marketing authorisations as well as lifecycle management". Furthermore, the review stresses that, before Law No. 61 came into force, "Russia

was one of the few emerging markets where registration requirements allowed market entry in parallel or shortly after the EU and US".

Some of the main changes of the Federal Law N 61-FZ are listed below:

- mandatory local registration of a clinical study for newly registered (including generics) or modified medicines,
- new timelines and fees for clinical trial applications and MAs,
- product labelling requirements,
- manufacturing licensing,
- and importation licences.

The law affected the majority of existing procedural guidelines and required development and adoption of new guidelines. The procedural changes were introduced by a number of decrees issued shortly after Federal Law N 61-FZ had come into force.

The Federal Law, On Amendment of the Federal Law "On Circulation of Pharmaceuticals" No. 429-FZ (hereinafter – the "Law No. 429-FZ") was signed on 22 December 2014. The Federal Law, On Amendment of Article 61 of the Federal Law "On Circulation of Pharmaceuticals" No. 34-FZ was signed on 8 March 2015. These legal acts introduce significant amendments into the Federal Law "On Circulation of Pharmaceuticals" No. 61-FZ dated 12 April 2010.[14]

Acts and Rules Used to Govern Veterinary Medicine and Committees:

- Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor): The Service carries out functions on control and supervision in the field of veterinary science.

- Federal State Institution "Russian State Centre of Quality and Standardization of Animal Drugs and Feeds." The Institution implements the state policy in the field of quality assurance of medicines for animals. It acts as a reference centre for scientific and methodological support of the Rosselkhoznadzor.

Federal Law "On the Circulation of Medicines" of April 2010, No 61-FZ[15]	This law regulates the preclinical research, the clinical research, the expertise, the state registration, the standardisation and quality control, the production, manufacturing, storage, transportation, import, export, advertising, sale, transfer, use and destruction of medicines.
Rules of "State Registration of Medicinal Products for Animals and Feed Additives" of April 2005, No 48.[16]	The rules establish a unified procedure for the state registration of domestic and foreign medicinal products for animals.
Standard regulation (GOST P 54763-2011).[17]	This standard applies to pharmacological, biological and homeopathic medicinal products for veterinary medicine and establishes general requirements for the content, order of development, harmonisation and approval of technological production regulations.
"Rules of production and quality control of drugs" of June 2013, N 916.[18] (Russian GMP rules, which are a literal translation of the GMP rules, functioning in the EU.)	The rules establish the requirements of the organisation of production and quality control of medicinal products for human and veterinary use.
The Law of the Russian Federation "on veterinary medicine" N 4979-1 of MAY 1993.[19]	The law regulates the relationships in the field of veterinary medicine.

General Regulatory Requirements for Veterinary Drug Registration[20]:

The list of documents that make up the registration dossier of medicine is defined in part 3 Article 18 of the Federal Law N 61 dated 12.04.2010 "On Circulation of Medicines". Article 30 of the Federal Law N 61 establishes the bases of amending the documents contained in the registration dossier, as well as the procedure for making such changes. The order of the Ministry of Health and Social Development of the Russian Federation No. 760n dated 26.08.2010 approved the form of "Application of statements for modification of the documents in the registration file on the registered medicine for a medical application". In addition, the Order of Ministry of Health of the Russian Federation of 22.10.2012 No. 428n approved the "Administrative regulations of the Ministry of Health of the Russian Federation on provision of state service for state registration of medicinal products for medical use", which, in particular, provides a procedure for amendments to documents contained in registration dossier for registered medicines.

The registration process in the Russian Federation can be divided into four stages as shown in Figure 1. First, the applicant submits the dossier, samples and reference standards to the Rosselkhoznadzor. The Rosselkhoznadzor validates the submitted documents in the second stage of the process within five days. The total period for the standard registration procedure including registration testing is 160 days. In an accelerated procedure, the registration procedure takes up to a maximum of 60 days.

In the final (for both the standard and the accelerated procedure) stage, the Rosselkhoznadzor provides its decision on the registration of the product to the applicant, which takes up to five days.

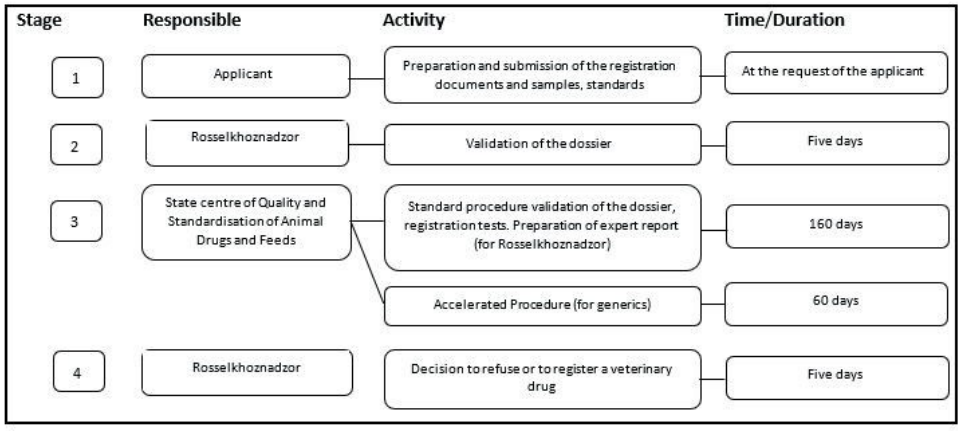


Figure 1 VMPs Registration Process in Russia[20]

Documents required for the registration[20]:

- Application form
- The legal address of the organisation that produces the medicinal product; names of the medicinal product, including international non-proprietary name scientific name in Latin, main synonyms; the original name of the medicinal product, if registered
- Documents confirming the registration of a medicinal product, if it is registered outside the Russian Federation
- List of components, their quantity and quality
- Instructions for the use
- Certificate of quality of the drug or supplements
- Data on the production of a medicinal product
- Methods of quality control of a drug or supplement
- Stability data

Results of preclinical studies of the drug or supplement

- Results of pharmacological and toxicological studies of the drug (toxicity, teratogenicity, mutagenicity, carcinogenicity, immunotoxicity, allergenicity, pharmacokinetics, MRL, literary review is possible)
- Results of veterinary clinical trials
- Mock-up, labelling, instructions for use
- Samples from three batches (necessary to conduct three complete analyses of the quality of the preparation in accordance with the requirements of the draft specifications), standard samples
- Proposals for the price for a drug

Regulatory Aspects and Requirements for the VMP Registration in the Russian Federation[20]:

Regulatory authority and address	Federal Service for Veterinary and Phytosanitary Supervision.
Validity of registration license	License is valid for five years.
Dossier requirements	NTD (Normative and Technical Documentation) should be submitted in Russian or have a certified translation into Russian.
Labelling requirements	Labelling is to be written in Russian.
Maximum Residue Limit MRL	Russia is a Member of Codex Alimentarius. Russia is a part of the EAEU (Eurasian Economic Union). MRLs (maximum residue limits) established by the CU apply to Russia. Russia has also a national MRL list, which differs from EU standards. For example, the standards for tetracyclines are even more stringent: less than 0.01 mg / kg in all standardised products compared to those recorded in the Codex Alimentarius (from ≤0.1 to ≤1.2 mg / kg depending on the product) and the European Union (EU) (from ≤0.1 to ≤0.6 mg / kg).
Quality standards	Valid quality standards are: Russian pharmacopoeia, GMP and CPP (Certificates of a Pharmaceutical Product) certificates, manufacturing licence.
Post-authorisation variation	MAH (marketing authorisation holders) are obliged to report any changes that they intend to make to the registration documents and provide exhaustive information on the reasons for these changes and their impact on the effectiveness, safety and quality of the registered medicinal product. Variations are reviewed within 90 working days.
Renewal	Before expiration date of previous registration, but not earlier than 180 days, the applicant is entitled to apply for re-registration of the medicinal product.
State register after authorisation	The registry information is available online.
Additional information	Clinical studies are accepted only in case they have been performed in Russia (this applies also for generics, new indications and line extensions).

According to the law "On circulation of medicines" the registration of medicinal products for human or veterinary use produced outside of the Russian Federation are accepted by the Russian NCA only after conducting a GMP conformity assessment for all manufacturing sites involved in the manufacturing process (including active pharmaceutical ingredients (APIs)). The GMP conformity assessment for veterinary products is conducted by Rosselkhoznadzor on the basis of decision of the Russian State Center for Quality Control and Standardization of Veterinary Drugs and Feeds by examination of provided documents and mandatory inspections of all manufacturing sites involved in the manufacturing process.

Conclusion

In all countries of the world, the registration allows allocation of a medicinal product in the respective pharmaceutical market. The main target of medicine registration in any country is the provision of its population with high-quality, safe and efficacious medicines. Therefore, the registration

is complex and time-consuming. The registration and import of veterinary drug plays an important role in order to market the product. In the Russian Federation, the veterinary medicine follows the registration pattern: "one law, two authorities" and is regulated by the national Ministry of Agriculture (separately from human medicine). The key legislation for veterinary medicines comprises the Federal Law N 61-FZ of 12-Apr-2010 on the Circulation of Medicines. The law is valid for both human and veterinary medicines.

The market for VMP will continuously expand in the near future. This assumption is based on the growing demand for meat of good quality in the emerging markets, and increase of western lifestyle in Russia, especially in terms of companion animals. As a result, that trend will attract a rising number of international pharmaceutical companies to invest in the animal health market. However, the new market will remain a big challenge, because of the increasing regulatory burdens implemented by NCAs (national competent authorities).

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