Chapter 13
Pharmaceutical Policy in Russia

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Abstract Pricing and reimbursement policies have changed significantly in Russia during the last 20 years, largely due to ongoing reform processes within the healthcare system. The current structure of the Russian healthcare system includes federal and regional levels with different requirements and funding allocations due to diversity in the population (average and population density), overall and per capita income, and other factors. The federal level is governed by the Federal Ministry of Health, which is responsible for the pricing and reimbursement policies in the country. Federal budgeting covers the majority of healthcare programs, while the regional budget provides additional financing for regional needs. Reimbursement of drugs is incorporated in these programs, along with other expenses (hospitalization, laboratory testing, and so forth).

In terms of pharmaceutical policy, inclusion of medicines into reimbursement lists includes two staged steps in Russia. In the first step, the drug must be included in the Essential Drug List (EDL) and a pricing cap is then applied. The upper margin of the drug price is determined as a referral price for imported medicines (based on a basket of 21 countries). It can also be based on drug development and manufacturing expenses and include regional markups specified for each region. Cost-effectiveness analysis is part of the requirement for submission of an EDL dossier in Russia. The second step in the process is the inclusion of EDL-listed drugs into federal healthcare disease specific programs (oncology, HIV, and so forth). Regions can establish healthcare programs in addition to the federal activity based on regional requirements and their own regional funding allocations and budgets. There are different needs within the healthcare system at federal and regional levels; including hospital and industrial corporations who have their own healthcare

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services. This can contribute to challenges in implementation of uniform approaches to Health Technology Assessment (HTA) at different levels and in the different regions.

13.1 Overview of the Russian Federation

The *Russian Federation* (РоссúйскаяФедерáция, *Rossiyskaya Federatsiya*), commonly known as *Russia (Rossiya)*, is a transcontinental country extending over much of northern Eurasia (Asia and Europe). Russia has a fascinating history and recent changes in the health care system and demographics of the population have had a significant impact on pharmaceutical policy and practice. These are addressed in this chapter.

In Russia in 2014, demographic analyses highlight that the birth rate exceeded the death rate, resulting in a net population growth. The State Statistical Agency reports that the population of Russia is 146 million people, with an average life expectancy of 65 years for males and 76.4 for females. The most significant causes of mortality include diseases of the circulatory system (653.9 per 100,000), cancer (201.9 per 100,000), and injuries (129.9 per 100,000) [1].

13.2 The Health System of the Russian Federation

The current healthcare system of Russia is a fusion of features from the former Union of Soviet Socialist Republics (Soviet Union) with changes made by the Russian Federation in the time since the dissolution of the former Soviet Union in December 1991. Under the guidance of the Soviet Union the system was created as a centralized structure to ensure maximum efficiency of managerial decisions supported by tight administrative control. The objectives of the system at that time were to ensure uniform principles of healthcare organization and access to healthcare for the entire population of the country at the expense of a state-funded budget [2–4]. Nowadays, the centralized system of healthcare is put in place by the Federal Ministry of Health and is supported by the Ministries of Health in 85 regions, with their own budgets and regional development programs. Expenditure on healthcare delivery and patient treatment is provided by Federal and Regional Target Programs supervised by the Federal and Regional Ministries and a budget is provided by either regional or federal state insurance funds. Reimbursement of pharmaceuticals is included in these programs alongside other expenditures [4, 5].

Under this current system, some expenses are covered by patients themselves or by other sources including additional voluntary insurance (private insurance) and corporate finance allocations for employees. Currently, the healthcare system in Russia has three dimensions that are continually changing and include financial

sources, institutions, and management. The following sources contribute to the healthcare budget:

1. State-funded programs using federal and regional budgets. These programs have specific target populations dependent on disease state or patient status or disability (oncology, AIDS, disabled, pediatric, etc.).
2. Insurance funds (obligatory and voluntary).
3. Patient self-funded ("out-of-pocket" expenses).
4. Corporate funded programs (national air company "Aeroflot", Russian Railways, etc.) with their own budgets and structures and provide in and outpatient services.

All of the above is managed by Federal and Regional Ministries of Health, corporate healthcare management (for the corporations), and municipal authorities. Additionally, there are insurance funds: voluntary schemes, which are flexible in decision making, and obligatory schemes, which need to distribute resources according to policies and procedures.

Some interactions between these healthcare components are very formal (such as the distribution of budgets from obligatory insurance funds to state-budgeted hospitals), while others are flexible (the same hospitals can also accept money from voluntary insurance funds, patients or in accordance with contracts with corporations) and can be changed within a relatively short period of time.

Drugs are distributed via networks of community pharmacies or hospital pharmacies for inpatient clinics. The State Program for Healthcare Development prioritizes prevention of diseases with special attention on the health of mothers and children [6]. There is also a focus on the implementation of innovative medical technologies into practice: target therapy using biologics, noninvasive methods of breast cancer diagnostics, etc. In 2015, the main healthcare objective was the prevention and decrease of cardiovascular disease burden, with nearly half of deaths caused by this (49.9%) in Russia [1].The strategies declared by the Federal Ministry of Health include a comprehensive set of activities, including population awareness regarding the adoption of healthy lifestyles, additional education in this area for healthcare practitioners, and general improvement of healthcare management [1]. This involves adaptation of the whole system to new conditions, which include the economic situation, budgeting, recent changes in healthcare technologies, and management structure and methods.

13.2.1 Federal Level

The Ministry of Health is the Supreme Health Authority in the Russian Federation [5]. It is headed by the Minister appointed by the Prime Minister upon approval of candidacy by the State Duma.

The Ministry of Health sets policy in Russia and officially retains the right to monitor the regional health and enforcement of decisions in healthcare entities of the Russian Federation. However, the extension of the powers of local authorities,

and primarily their right to form their own budget, means that the Ministry can no longer count on the fulfillment of its central instructions.

The budget of the Ministry of Health is established by the Ministry of Finance. This budget also supports scientific research institutes, scientific centers, and medical educational institutions working under the supervision of the Ministry of Health. The federal healthcare budget is established and approved by the government as part of the general federal budget. The Ministry of Finance distributes funds to the appropriate ministries and these ministries (Federal Ministry of Health as well) supervise and manage proper distribution of the budget according to the healthcare programs. The Federal Ministry of Health is, therefore, responsible for these activities at the federal level. Regional Ministries of Health have the same responsibilities and communication lines at a regional level and supervise regional programs in addition to the federal ones. Thus, in each region there are federal programs and additional regional programs with attached federal and regional sources of funding and subsequent budgeting.

The public healthcare system includes the Ministry of Health of the Russian Federation, the Regional Ministries (Departments) of Health of the republics of the Russian Federation, the bodies of health administration of the autonomous region, edges, areas, cities of Moscow and St. Petersburg, and the State Committee for sanitary and epidemiological supervision of the Russian Federation. This system also includes state-owned hospitals and outpatients clinics, research institutions, educational institutions, pharmaceutical companies and organizations, pharmacies, institutions of forensic medical examination, and enterprises for the production of medicines and medical equipment.

13.2.2 Regional Health Care

The regions of the Russian Federation are obliged to ensure the fulfillment of Federal Targeted Programs, primarily aimed at monitoring the epidemiological situation and the fight against infectious diseases, but they do not report to the Federal Ministry of Health. The regions have their Ministries of Health reporting to regional authorities and are capable of developing regional healthcare programs according to regional needs and opportunities in addition to those at the federal level.

13.2.3 Municipal Health Care System

The municipal healthcare system includes municipal governments and municipally owned clinical and research institutions, pharmaceutical companies and organizations, pharmaceutical institutions, institutions of forensic medical examination, and

educational institutions which are legal entities and operate in accordance with the legislation of the Russian Federation and the local legislation.

13.2.4 Private Health Care

Private healthcare is available in the Russian Federation which includes provision by private clinical institutions and community pharmacies with staff engaged in private medical practice and pharmaceutical practice. The System of Voluntary Health Insurance (VHI) includes several private insurance companies. Funding of VHI is provided partially by the employer, and partly by the patient. The patient also contributes the full amount of the premium if the employer does not pay into the scheme. The list of medical services that are covered under the policy varies in the different VHI programs and includes: medical care only in emergency cases and certain types of inpatient and/or outpatient treatment. Certain services in dental care may also be included in the VHI program.

13.2.5 Federal and Regional Insurance Funds

Insurance funds were a significant component of healthcare system reform in the Russian Federation in the 1990s [4, 5]. Government policymakers had to improve the national healthcare financing arrangements and to move the healthcare system into an open market style of management, which was expected to increase economic efficiency, quality, and improve access of medical care for all Russians. Under the new scheme of financing, key resources were the funds of mandatory medical insurance including the Federal Fund of Compulsory Medical Insurance and Regional funds, one in each region ("subject of state"), of the Russian Federation.

Insurance funds collect premiums and distribute resource for the provision of healthcare in their territories. Working citizens pay about 3.6% (3.4% to regional funds and 0.2% to the Federal Fund) of their wages, while the contribution for non-working individuals (children, pensioners, unemployed, and so on) is paid for by local authorities. Regional funds transfer the received budgets to the insurance companies (also referred to as health insurance organizations) or branches of the regional funds and on behalf of the insured, enter into contracts for medical services with clinical institutions. Federal and territorial funds are public nonprofit organizations. The Federal MHI Fund is a legally independent organization and is not under the Ministry of Health, but it monitors its activities through their representatives on the Board.

The Federal Insurance Fund oversees the activities of territorial funds; the situation of the compulsory health insurance system corresponds to the position of the Regional Health Authorities. Federal funds are primarily required to manage the entire system and to monitor the financial equality within the regions.

13.2.6 Insurance Companies

The next key element established by Russian Federation law on health insurance is an independent organization carrying out payment for medical services on behalf of the insured population. Based on analysis of the Federal Insurance Fund [7] there are two types of organizations: independent insurance companies and branches of regional insurance funds, who take on the role of insurance companies in their absence in the area. Insurance companies receive funds for each insured person and select preferred medical institutions to provide medical services to the insured population. Insurance companies are able to promote competition between those medical institutions to encourage them to reduce costs and improve the quality of medical services. Insurance companies monitor the volume and quality of medical services and in accordance with their findings, issue medical institution funds.

There are insurance funds for compulsory medical insurance and the objective of these is to distribute and deliver federal and regional funds. The flow of remuneration is "one-way" from federal or regional budgets to the patients. These insurance companies are expected to follow federal and/or regional healthcare programs and do not have the right to make fund-related decisions at their own discretion. Another type of insurance company (Voluntary Health Insurance) operates through patient payment of levies/premiums, or any other entities. These pay for those patients associated with corporations, etc., and not related with state (federal or regional) healthcare programs. These Voluntary Health Insurance companies are privately owned and are more flexible in their decision making around the programs they provide to their patients. A few years ago, there was a considerable gap between these two types of insurance companies in terms of what they offered but now these differences are reducing and these days compulsory insurance funds can provide programs for voluntary health insurance premium holders.

Insurance companies can organize their activities in a variety of ways. This includes providing paid medical services to a defined population on pre-agreed rates, or to establish general practice funding per capita, etc. The number of insurance companies peaked at the end of the 1990s when there were approximately 1350 insurance companies in operation, while now there are less than 300, and their numbers continue to decline.

13.3 The Pharmaceutical Situation in the Russian Federation

Official statistical data supported by independent research by private consulting company "DSM Group" indicates that the Russian pharmaceutical market is still growing in national currency terms, averaging 14% growth year on year. Based on 2014 data, in 2015 the market growth in national currency was expected to be 12% (1.3 trillion Russian Rubles). In foreign currency terms (US dollars, USD) a decrease of market

volumes of 18% was seen, down to a figure of 24.8 billion USD [1, 8]. This situation is due to the difference in exchange rates between the local currency being the Russian Ruble and the US dollar (USD). The market in terms of number of packs is growing, and the price for the average pack is also growing in local currency. At the same time, the exchange rate between local currency and the USD has been decreasing due to economic crises and inflation. As a result, the market growth in terms of USD is seen to decrease. The low value of local currency relative to the exchange rate provides advantages for local manufacturers (less to pay) and disadvantages for imported products including pharmaceuticals – they sell in local currency, they pay more in USD. This situation makes local (domestic) manufacturing beneficial and provides an opportunity for the Russian government to decrease prices for medicines as locally produced products cost less due to reduced manufacturing and transportation costs, among other factors.

The share of public procurement market was in the range of 28–30%, or approximately 309 billion Rubles [9, 10]. The commercial sector procurement amounts to 776 billion Rubles. The authors use the term "public" for state-budgeted programs of healthcare (including compulsory health insurance) and "commercial" for any other (out-of-the-pocket or corporative purchases, voluntary health insurance.)

The share of domestically produced medicines in 2014 amounted to 24.3% in monetary terms and 55.3% in terms of the quantities of packs sold. Over two-thirds (68%) of drugs listed on the Russian Essential Drugs List (EDL) are produced in Russia. According to IMS Health data, Russia ranks 11th of 15 countries for high per capita consumption of pharmaceuticals (in USD). According to the forecast of the Economist Intelligence Unit (EIU) by 2018, Russia will drop to occupy the 17th place ranking. A portion of medicines manufactured in Russia are exported to Uzbekistan, Ukraine, Kyrgyzstan, Azerbaijan, and other countries, but the quantities are less than the amount of drugs imported into Russia – i.e., imports are greater than exports [11, 12]

From the end of 2014, the pharmaceutical market has been under the influence of the general economic situation in the country, which has included devaluation of the national currency and a slowdown in the economy. The geopolitical situation and sanctions against Russia have resulted in changes in the law regarding prices of medicines on the EDL. The new regulations were also aimed to support local manufacturing of medicines [13]. In accordance with this decree, tenders are required to be provided according to the International Non-proprietary Name (INN) and the customer is expected to reject any medication manufactured in countries other than the member states of the Eurasian Economic Union in the case that there are at least two medicines produced in those countries.

According to experts surveyed by private consulting company DSM Group, professionals in the pharmaceutical industry are particularly concerned about:

- The economic situation in the country
- The necessity of improving the legislation that regulates the pharmaceutical industry
- Necessity to increase funding of healthcare programs and to support local business in the pharmaceutical industry
- The international political situation and its associated economic risks [8]

13.4 The Regulatory Environment in Russia

The Russian laws, which influence State affairs and the development of the health sector and the pharmaceutical industry, include:

- Federal law dated 21 November 2011 No. 323-FZ "About bases of health protection of citizens of the Russian Federation" [5]
- Federal law dated 12 April 2010 N 61-FZ "On circulation of medicines" (with amendments and additions) [14]
- Russian Federation Government resolution from February 17, 2011 N 91 "About the Federal target program Development of pharmaceutical and medical industry of the Russian Federation for the period till 2020 and the further prospect" [11]

The principles laid down in these laws and recent changes prioritize quantitative and qualitative development of the domestic pharmaceutical industry and are expected to reduce the dependence on imported medicines and to increase the share of Russian medicines in the domestic market. This provides an opportunity to reduce the risk of political bans and the high cost of imported pharmaceuticals compared to those manufactured in the Russian Federation. Measures include:

- Restriction in the participation of products from foreign producers in budget tenders, when medicines produced in the countries of the Eurasian Economic Union are available.
- Encouraging foreign manufacturers to establish a full production cycle in Russia and invest in Russian companies through the provision of benefit such as the opportunity to secure investments or obtain funding for transferring of manufacturing in the country.
- Separate pricing methodology for medicines in different price segments, including imported medicines compared to those manufactured locally.
- Transition to the GMP standards effective from 1 January 2016 in the Eurasian Economic Union. In order to create a unified market among the Eurasian Economic Union on 29 May 2014, member states signed an agreement outlining common principles and rules of engagement for circulation of medicinal products and drugs including registration of medicines and medical devices, thus they unified the standards of production and clinical trials.

Financial support for Russian manufacturers – for example, a Russian pharmaceutical company, which develops medicines is entitled to receive subsidies or partial compensation for the cost of debt loan payments, according to the Decree of the Government # 214 [15].

13.4.1 Medicines Regulatory Authority

The Ministry of Health is the medicines regulatory authority in the Russian Federation along with Regional Ministries of Health, in each of the 85 regions [8].

The Federal Ministry of Health is responsible for registration (market access) and pricing processes associated with pharmaceuticals. This function is performed by the Department of State Regulations for Medicine's Circulations in the Federal Ministry of Health.

There are the following Divisions in this Department:

- Division of Registration
- Division of Clinical Research
- Division of Regulation of Restricted Medicines
- Division of Pricing for Medicines from the EDL

The responsibility for registration of medical devices is still held by *Roszdravnadzor. This* agency is also responsible for control of the safety and quality of registered medicines and medical devices in Russia.

There are three institutions within *Roszdravnadzor*:

- Center of monitoring and clinico-economical expertise, which is responsible for the evaluation of the quality of healthcare, development, and use of medical devices and the storage and wholesaling of pharmaceuticals).
- Information and methodical center on expertise, analysis, and counting of medical products [16].
- Russian Research and Test Institute for Medical Devices [17]. This organization conducts testing for the purpose of registration and certification on request of the Department of Registration from the Federal Ministry of Health [18].

Quality control of medical products at all stages of the supply chain including transportation to the pharmacy, storage, and delivery to patients is the responsibility of the Roszdravnadzor. The main responsibilities of this organization include the state quality control of medical care, licensing of medical activity, and verifying the correctness and effectiveness of the use of budgetary funds.

13.4.2 Quality control

Medical Devices Roszdravnadzor carries out registration of medical devices, amendments to registration documents, and registration certificates for medical products and provides permission to import medicinal products. Roszdravnadzor also coordinates and issues permits for clinical trials of medicinal products, carries out control over the circulation of medical products, monitors the safety of medical devices, and issues licenses for the production and maintenance of medical equipment.

Pharmaceutical Products Roszdravnadzor supervises clinical and preclinical research, monitors drug safety, drug quality control, detection of inappropriate medicines (rejected or counterfeit), and issues permits for import and export, and licensing of medicinal products [19]. The agency also supports and evaluates the database for drug safety reports.

13.4.3 Pharmacovigilance

Roszdravnadzor carries out the statewide function of conducting safety monitoring for medicinal products in circulation within the territory of the Russian Federation. The stakeholders involved with the circulation of medicines include doctors, pharmaceutical companies, and patients and they are obliged to inform Roszdravnadzor about any cases of unlisted side effects, unexpected or serious interactions for registered medicines and those that are undergoing clinical trials. In the framework of monitoring the safety of medicines, Roszdravnadzor carries out an analysis of periodic reports on the safety of medicines received from manufacturers and developers of medicinal products. Roszdravnadzor carries out analyses under the framework of monitoring drug safety information. The results of these analyses are sent to the Ministry of Health for decision making about amendments to the instructions on the use of drugs, the suspension of their circulation or re-introducing the circulation of drugs [14]. It is interesting to note that in the Russian Federation, community pharmacies do not usually have two-way communication with patients. Patients receive or buy drugs in these outlets but in case of adverse events or any other reaction they refer to doctors (not pharmacies) and thus pharmacies cannot be considered as a reliable source of information for pharmacovigilance reporting. Pharmacies are expected to report adverse reactions if they have patient information about them; however, the probability of pharmacies doing so is very low.

13.4.4 The Presence of Counterfeit Medicines in the Russian Federation

Roszdravnadzor carries out regular inspections and identifies rejected and counterfeit drugs. Defective drugs are produced legally but are inconsistent in terms of presence of active ingredients in the medicine or the inclusion of impurities, or either noncompliance with labeling requirements. Roszdravnadzor prepares a list of defective and adulterated products, which it publishes and distributes to pharmacies. According to Roszdravnadzor expert opinion, spot checks revealed that only a part of the substandard and counterfeit products are available in the Russian Federation. It is estimated by experts that 7–8% of Russian pharmaceuticals are substandard and that 0.5–0.6% are counterfeit. Most often counterfeit drugs lie in the middle price segment with a value from 150 to 500 Rubles (2 – USD 10 per pack). In this regard, the establishment of a monitoring system of defective products is relevant and important [18].

13.5 The Medicines Supply System in the Russian Federation

There are two ways for funding the distribution and access of pharmaceuticals in the Russian Federation. These include out-of-pocket where the patient pays the full amount (via municipal and private pharmacies) and in accordance with the

programs of budget financing through the State. The surveys performed by the DSM Group of companies indicate that the share of publicly funded procurement is in the range of 28–30% of the total pharmaceutical expenditure across all funding mechanisms [8].

There are three main levels of procurement which are usually undertaken in the format of tenders including federal, regional, and at the level of individual medical institutions. The main criterion for selection is the lowest price compared to competitors [11]. Tenders are drawn on the basis of the International Nonproprietary Names (INN). If INN presents two or more manufacturers from the Eurasian region, then parties with drugs manufactured in other countries are not permitted to participate in the tender process [11].

Once procured, the drugs are delivered to clinics and pharmacies, both municipal and private. Municipal and private pharmacies have different ownership structures. Historically, all pharmacies where patients could source medicines were municipal and patients also received medicines in hospital pharmacies (as departments within hospitals) according to state-budgeted healthcare programs. Any pharmacy must hold a supply of medicine according to the list (the minimal register of drugs, which must be in any pharmacy) and they may stock supplies beyond this list. In the 1990s, privately owned pharmacies began to emerge and were more flexible compared to government-owned municipal pharmacies. These pharmacies generally have more medicines available but medicines are often highly priced as compared to municipal pharmacies. Nowadays, the difference between the two types of pharmacies is not so obvious (ownership is different but the legal requirements are the same) and in some cases they attract the same group of patients.

In Russian hospitals, medicines for inpatients are stored in the pharmacy and are issued at the request of attending physicians. For patients with disabilities and for vulnerable populations there is a program called "Additional Medicinal Maintenance". In this scenario, drugs are dispensed from a municipal pharmacy, free of charge.

Corporations and agencies that are supported by federal funding also need to perform tenders for drug procurement. Private healthcare institutions are not required to comply with this law and they can purchase medicines according to their corporate procedures. However, this segment of the market is relatively small, the exact figure is unknown and this is an interesting area for future research.

13.6 The Financing of Medicines

The financing of medicines in the Russian Federation is based on federal, regional, and municipality budget funds, as well as insurance funds and budgets of corporations and other private agencies. In terms of financing, the "Corporations" are private or at least are run in a fashion that is most like a private corporation. At the same time, one of the owners can be the Russian Federation government or the company can be a monopolist. The biggest examples are "Gasprom", "Russian Railways", and "Aeroflot." These corporations

have a huge workforce, which requires healthcare services, including the provision of medicines and they can make decisions regarding medical services at their own discretion. These companies can also allocate healthcare budgets based on their income and profits and also decide the kind of healthcare strategy they wish to use. For example, a few years ago "Gasprom" and "Russian Railways" decided to unite their medical services and now there is one combined healthcare system that provides services for both organizations, and this was affordable due to economies of scale.

According to official statistical data and the DSM Group of companies analyses, healthcare costs amount to 3.3–3.5% of gross domestic product (GDP) per capita [20, 8]. The cost of consolidated federal and regional budgets amounted to 1024 billion (35.9 per cent) in 2013, while the budgets of the federal insurance fund amounted to 1521 billion rubles (53.3%). The remaining 10.2% was "out-pocket payment". Of these funds about 309 billion rubles was spent on medicines procurement. Federally targeted programs include the national project "Health", vaccination, prevention, and treatment of AIDS, tuberculosis, cancer, psychiatry, diabetes, pediatrics, and orphan diseases program ("7 nozologies").

Regional budgets are utilized for regional target programs in addition to federal ones. Regional programs are not simply localized replications of the federal program. In fact, regional programs cover those aspects that are not covered by the federal ones. For example, if a patient has cancer then the federal oncology program will cover that. If the patient needs additional procedures or medicines (some more MRI tests, new and expensive target therapies, etc.) these expensive interventions will be covered by regional programs if there is one in place, or by the patient in the case these funded programs do not exist.

Corporations and other private agencies finance their hospitals and procure drugs at their own cost in accordance with their needs.

13.6.1 Pharmacoeconomics, Medicines Pricing, and Access

13.6.1.1 Market Access: The Registration Process

All new medicines, including generics, combination medicines, new forms, and doses of medicines should be registered with the Federal Ministry of Health. There are stated time limits for approvals within the registrations process, which is expected to be no longer than 210 working days. Data from clinical research conducted in Russia are now a compulsory requirement for registration within the Federation. The exception to this rule is whereby data is available from a multicenter study where there was a Russian study center within an international program. Expertise to assess the registration portfolios is found within the expert center under the Roszdravnadzor. There is a fixed tax fee for the registration process to be paid to the appropriate agency [16].

13.6.1.2 The Pricing Process in Russia

The power of price setting for medicines paid "out of pocket" by the consumer is held by the manufacturer and typically the price depends on the market situation. The wholesale and pharmacy remuneration for these medicines is linear and they vary by region with the largest variance with prices being higher in the remote Northern part of Russia; for example, in the Yamal region where other consumer goods are also more expensive than in urban Russia [20].

Medicines are divided into two groups in the Russian Federation: locally manufactured (the price depends on prices for this drug in the country before inclusion into the EDL) and those drugs manufactured abroad [21, 22]. For drugs manufactured abroad, the price can be established based on the prices overseas. The price regulation is applied to medicines from the List of Vital and Essential Medicines (there are multiple names for this list and it is also called EDL). The upper price margin for EDL drugs on this list is fixed and this is based on referral pricing of the 21-country basket. This is in the context of this drug having been marketed abroad before. For locally manufactured medicines or those that had not been marketed abroad before, the procedure is based on the actual price of a medicinal product for a certain period of time and the actual production costs of drugs from the EDL.

The executive authority of the Russian Federation also fixes medicines prices to maximum wholesale and retail levels and also set a ceiling on profit margins. Thus, the pricing process is transparent and monitored at both federal and regional levels. The use of this method of regulation of prices for medicines in the Russian Federation prevented the uncontrolled growth of prices during the global financial crisis of 2008.

Final prices for medicines are stipulated and determined during the tendering process. Remuneration for the medicines from the List of Vital and Essential Medicines is available for those that have market authorization and for which the price was registered.

The level of value-added tax (VAT) for medicines in the Russian Federation is approximately 18%. The exception to the VAT is for medicines, which are manufactured in a pharmacy and some medical devices, such as bandages, devices for disabled patients, and so on.

13.6.1.3 The Reimbursement Process

There is a formal requirement for Health Economic Assessment (HEA) for the inclusion of medicines in the EDL. The decision to include a medicine is made on the basis of a dossier and a formal questionnaire, in which product features are valued by the number of points. Since 2014, there has been a requirement in the questionnaire to provide results of analyses of "cost-effectiveness". This allows the addition or subtraction of 1 point from the integral evaluation of the product. For comparison, the criterion of "cost reduction" allows the addition or subtraction from

1 to 9 points depending on the size of the effect. The final decision to include a medicine in the reimbursement list is made by the Cross-disciplinary Commission. Composition of the Cross-disciplinary Commission is constituted and approved by the order of the Ministry of Health. It formulates a potential list of drugs, which becomes the actual final list after approval by the government. This list is valid for a period of 1 year until the next revision is undertaken in the same manner. There are more than 600 medicines (international nonpatent names) in the Russian List of Vital and Essential medicines, but there are only half of the listed medicines available in most regions.

The inclusion of drugs in EDL makes possible further inclusion in the programs of budgetary financing, but it also means that there is a restriction on the price.

It is fair to assume that most readers may not have heard about a medicine reimbursement process. It may not be in common with other countries, but there is a list of the State Programs that allow patients to receive medicines for free. In other words, the reimbursement level is 100% for state-budgeted programs. The federal list includes seven most expensive diseases to treat, which include hemophilia, organ transplantation, onco-hematology, tuberculosis, human immunodeficiency virus (HIV), and vaccines, as per the national immunization calendar.

Regional State Programs include oncology and 24 rare diseases such as pulmonary arterial hypertension and juvenile rheumatoid arthritis. Also there is 100% reimbursement for all medicines from the hospital's formularies for the inpatient sector. In the Russian Federation, there is also a form of subsidy through copayment: *50%* for some vulnerable groups (unemployed adults with disability of II and III groups) on the regional level and *13%* – for all employed citizens paying for their children or other direct relatives. EDL is the base for all lists mentioned above.

13.6.2 The Role of HTA in the Decision-Making Process

Now at the federal level, for inclusion in the Russian EDL, there is a formal requirement to provide the results of a cost-effective analysis as one of the elements of the Health Technology Assessment (HTA). HTA is conducted by independent experts or expert organizations, and it is a compulsory part of a dossier for inclusion in the EDL. Currently, there are no common standards and quality criteria for the procedure of conducting an HTA. In fact, there is no authorized HTA agency in Russia. Different participants in the healthcare market (doctors, HTA experts, decision makers and payers, patients) have different views on the issue. The creation of Federal HTA as an institution requires good relations with all parties involved in this process, as well as making it transparent. One of the main objectives, therefore, must be to develop good communication with all healthcare market participants. And this is indeed an important step to make HTA a reality.

13.6.3 The Perception of HTA by Health Care Market Participants

A survey of experts has been undertaken to assess the current perception of HTA by participants with different roles in the Russian healthcare market in 2015. The survey involved Russian experts in HTA, members of Regional Ministries of Health, representatives of industry (representing market access), specialists from medical schools and representatives of Patients' Advocacy Groups and State Insurance Funds.

Fifty-one surveys were returned from 78 (response rate = 65.39%) and nonrespondents were largely specialists from insurance funds and patient advocacy groups (see Table 13.1). The percentage of experts who gave an explanation of the term "HTA" according to the WHO definition was high in the group of HTA experts (83%), and industry representatives (foreign companies) (75%) and moderate for employees of Regional Ministries of Health and Healthcare Practitioners (both 60%). HTA is the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. It is ideal that the HTA be conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods. The survey also indicated the necessity to implement HTA educational programs into medical schools and programs of continuing education for healthcare specialists. The responses provided by insurance funds and patient advocacy groups were expected due to their recent emergence in the Russian healthcare sector. High rates of engagement for industry representatives (foreign companies) can be explained by their participation in the process of data generation for the global value packs for their products.

The survey also indicated that the main decision maker on the inclusion of medicines within the EDL and budgeted healthcare programs (federal and regional) were the staff of the Ministries of Health (4.7–4.8 points of 5 max) along with the "Cross-disciplinary commission" (3.2–3.5 points of max 5). These two categories

Table 13.1 Percentage of completed surveys and answers compliant with the WHO term "HTA"

Role in the market	Compliant to WHO	Not compliant to WHO	Completed surveys (%)
HTA experts	83	17	100
Industry (market access)	75	25	100
Regional Ministries of Health	60	40	100
Healthcare Practitioners (GCPs)	60	40	60
The staff of the research institutes/ universities	18	82	100
Insurance funds	n/a	n/a	0[a]
Patients' advocacy groups	n/a	100	9

[a]Twenty-one sent out 0 returned

Table 13.2 Influence of various stakeholder groups on the budgeting of pharmaceuticals in the Russian Federation

Experts and institutions	EDL	Federal programs	Regional programs	Hospital lists
Federal Ministry of Health (FMoH)	4.8	4.8	1.8	2.0
FMoH external consultants ("Cross-disciplinary commission")	3.2	3.0	1.7	1.8
Regional Ministry of Health (RMoH)	1.4	1.0	4.7	3.2
RMoH external consultants ("Cross-disciplinary commission")	1.6	0.7	3.5	2.7
Industry	2.2	2.2	2.3	2.5
Universities (high medical schools)	1.7	1.5	1.3	1.4
HTA experts	1.9	1.5	1.4	1.3

were followed by the industry (2.2–2.5 from 5 max), in third place and experts on HTA (1.3–1.9 points). The least influential were the employees of medical schools who were indeed not involved in the decision-making process (1.4–1.7 out of 5 points max – see Table 13.2).

13.6.4 Multiple Levels of HTA Use

HTA should follow finance flows and decision making to distribute budgets effectively. The healthcare structure in Russia now includes several levels of decision making: federal, regional (in each region according to local conditions), hospital level (like HTA in Italy), and corporate level (something new but close to different HTAs in the United States). At the federal level, the decision should be related to EDL and federal healthcare programs. Moreover, there is a formal requirement for "cost-effectiveness" analyses for EDL inclusion. The next step is the regional HTA level for creation of regional programs. Below this is the hospital level.

HTA can be used to compile lists of medicines for federal and regional programs. It is difficult to use it for purchasing of drugs according to state budget purchasing [23]. Under this scenario, the INN must be used for tenders, with the exception of orphan drugs. In this case, the generic product would have price advantages and would probably be seen as more beneficial than the originator branded drug. This tendering process helps to decrease direct medical costs (expenses for drugs) but does not take into consideration "cost-effectiveness" or any other types of clinical-economic analyses. Only privately funded hospitals (or "commercial" departments of hospitals) can purchase medicines at their discretion and based on HTA data, because they are not government funded (i.e., they are not state budgeted). Based on this it is expected that private hospitals (or their "commercial" departments) will also be the first ones to implement HTA at the hospital level.

Opportunities for HTA implementation at the regional level are under consideration, but the need for the rational use of healthcare resources according to regional characteristics obviously exists.

13.6.5 Hospital Level

Currently, the possibility of using HTA at the hospital level is being discussed, but not to a great extent. Some medical institutions have the opportunity to use part of the funding for drug procurement in accordance with their own needs. Those hospitals which receive state budgets (federal, regional, or municipal) must follow tendering procedures in order to purchase drugs. As a result they will obtain medicines according to the INN (international nonproprietary name) at a minimal price. In the case when there is competition between brand name and generic drugs, it is most likely that the generic will be successful. This algorithm makes it possible to decrease expenditures and manage within budgets. On the other hand, it does not take into consideration parameters such as efficacy, efficiency, or cost-effectiveness. Only those medical institutions (private or corporate with independent (not state) funding), which do not receive non-state-budgeted funds (and thus they are not the subject of this legislation) can take these parameters into consideration and purchase drugs based on cost-effectiveness. Based on this, it is likely that private hospitals would be the first to implement HTA as soon as they have their own budgets and have flexibility to implement their version of rational use of medicines into their own practices.

13.6.6 Agency Level

Large corporations usually have individual employees with specific needs requiring healthcare and the assessment of medicines use. In the Russian Federation such organizations include medical services for the Russian Railways, civil aviation, and Ministry of Internal Affairs, among others. The number of employees in these agencies is large enough to sustain health programs and so these agencies have an opportunity to fund health programs relevant to occupational and professional activities of their employees.

The Federal Agency for Research Organizations (FANO) is responsible for the funding of subordinated research institutions, which are involved in the development of innovative medical technologies according to the federal program of pharmaceutical industry development [13, 24]. The focus is on developing technologies and the HTA methodology is used to assess the feasibility of developing drugs, devices, diagnostic methods, prevention and treatment as well as the evaluation of clinical and economic effectiveness of drugs in phase IV clinical under the direction of FANO. There is also a focus on venture assessment and development and FANO has budgetary discretion regarding which technological development is to be supported.

In 2015, an Expert Council for the assessment of new medicines, devices, diagnostic methods, prevention and treatment of the FANO was established. Expert and technical support expertise for this Council provides the “National Public Health Research Institute named after Semashko” [16]. The objectives are to develop

expertise to conduct health economic evaluations for medical technologies before and after market authorization, as well as market scanning and estimating effectiveness in future markets. The establishment of an institutional structure, which depends neither on industry nor on the Ministry of Health, creates the potential for its use as part of developing the HTA system in Russia.

13.6.7 Generic Medicines

The use of generic medicines in clinical practice provides an opportunity for effective drug supply to a wider Russian population at a lesser expense to the individual and/or to the State. The Russian Federation legislates and gives priority to generic drugs in competitive bidding. Another advantage of utilizing generic medicines is the constraint of participation in tenders by foreign companies, if the tenders involve at least two companies representing the countries of the Eurasian Union (which produce mainly generic drugs) [23, 25]. Empirical data on the ratio of the use of generics and originator branded medicines is not available in the Russian Federation.

13.7 Rational Medicines Use

Currently, a comprehensive system, which evaluates the rational use of medicines in Russia, is under establishment with different elements of the system being under the responsibility of various authorities. The following indicators are used for that purpose: clinical efficacy and safety including risk of appropriate use (GPs); reduction of expenses (payers); limiting the spread of antibiotic use including resistance and sensitivity (GPs). The meaning of rational use of medicines differs and varies by stakeholder group and this also presents challenges as funders having a focus on financial aspects and practitioners on clinical effectiveness.

13.7.1 Medicines Use in General

Medicines are provided free of charge for treatment received by individual patients in hospitals. In this case, the doctor prescribes the drugs that are available in a hospital pharmacy, procured in accordance with the federal and regional programs budget financing or formulary. There are clinical pharmacists working in the hospitals and they are making recommendations. More recently they have started to collect and assess other information available relating to economic effectiveness. At the same time, there is restriction in the clinical choices available to them based on the tendering system. Patients receive free medicines at the municipal stores in accordance with the Federal program of Additional Medicinal Maintenance (DLO).

Medicines are also available in municipal and private pharmacies, but in this case, patients have to reimburse the costs themselves and no clinical activity occurs through these medicines outlets.

13.7.2 Essential Medicines List, Selection of Essential Medicines, and Standard Treatment Guidelines

Currently, there are three main types of formal documents, which are approved by the Ministry of Health:

Only medicines from EDL can be included in federal and regional programs of drug supply. The upper limits rates are estimated for the medicines from EDL. It is the pricing policy in Russia.

- Standards of care (indicate the frequency of use of drugs for the treatment of diseases).
- Orders of providing medical aid (a list and sequence of actions of the physicians in the diagnosis and treatment of diseases).
- Clinical guidelines are only recommendations and are taken into account when creating the standards and orders of providing medical aid.

There is no one single association responsible for overseeing evidence-based medicine in the Russian Federation. In terms of clinical guidelines, the situation is the same as in many other countries. Guidelines are usually published on web pages of General Practitioner (GPs) associations [1, 9, 20, 26]. Sometimes international guidelines are used as it is, or adapted within the Russian context.

13.7.3 Prescribing Behavior and Factors Affecting Prescribing Behavior

Prescribing behavior has been widely discussed within professional associations and on internet forums in Russia. However, not many peer-reviewed publications on the matter are available. Review of forums and personal communications with Russian doctors indicates that their preferences significantly influence the list of prescribed medications that a patient may receive. In practice, many GPs prescribe those medicines which they use in daily practice. They also receive information from representatives of pharmaceutical companies but this information can be biased. Information from literature and scientific events is more reliable but considerable effort is needed to change the prescribing behavior of Russian doctors. It is thought that only a relatively small proportion of GPs actively look for information across a range of sources. The large majority of GPs accept information from the pharmaceutical industry through communication with medical representatives who are interested in their product being used as first line therapy. As such there is the

potential for representatives to be biased in the way that they present information about their products.

Patients may obtain information about drugs from internet forums and specialized web-sites or from patient advocacy groups.

Review of information available about prescribing behavior indicates that the activities of the pharmaceutical industry as well as perception of efficacy and safety criteria by GPs and patients can influence the market share that individual medicines have. This is anecdotal and a systematic approach needs to be taken in the Russian context to better understand this phenomenon.

13.7.4 Medicines Promotional Practices

In Russia, this includes medical conferences around specific themes, and interaction between company representatives and doctors. There is specialization among employees of pharmaceutical companies depending on their target population. As a general rule, GPs from outpatient departments of hospitals interact with the medical representatives, key opinion leaders communicate with the medical specialists of the pharmaceutical companies while decision makers with financial responsibilities are approached by market access staff. As outlined previously, the pharmaceutical industry can have considerable influence on what is selected to be prescribed from the approved list of pharmaceuticals. This is largely through the provision of information about their products and interactions between pharmaceutical company representatives and medical staff.

13.7.5 The Role of the Pharmacist in Russia

There are two main groups of specialists with different backgrounds and roles pertaining to medicines in the Russian healthcare system. The pharmacist is responsible for drug storage and distribution at any pharmacy or hospital. Routinely if they work at community pharmacies they advise their clients regarding medicines and they are also capable of performing such procedures as measuring blood pressure and blood glucose levels. At hospitals, pharmacists do not need to advise patients or perform clinical procedures but their focus lies not only with storage and distribution of medicines but also with their preparation (mainly infusion solutions).

Pharmacists are responsible for storage, preparation, and distribution of medicines in pharmacy (hospital, municipal, or private) and clinical consultations. In the case of "out-of-pocket" medicines, they can recommend the treatment. Self-treatment is still wide spread among Russian citizens, so the role of pharmacists for recommendation of nonprescription drugs is substantive. There is a list of medicines which cannot be sold in the pharmacy without a prescription including drugs used in psychiatry, opioid drugs, and some others.

Clinical pharmacologists advise physicians on the clinical efficacy and safety of drugs. These medical specialists have graduated from High Medical School with

appropriate specialization. Clinical pharmacologists are part of the representative team of the "Cross-disciplinary Commission" of Federal or Regional Ministry of Health and are responsible for the creation of reimbursement lists for medicines. Mostly these specialists are present in Federal Medical institutions or some hospitals in the larger cities such as Moscow and St. Petersburg

In the case of Moscow, which is divided into 12 regions, there is a position of a clinical pharmacologist in each region which suggests a lack of these professionals.

13.7.6 Pharmaceutical Care Interventions (PCI) and Assessment of Community Pharmacy Practice

Compliance with procedures that apply to the use of medicines and assessment of community pharmacy practice is conducted by Roszdravnadzor during regular and "for case" checks. Pharmaceutical care interventions (PCI) are not the main responsibility of pharmacies in the Russian Federation. The majority of such activities are being undertaken in medical institutions. Pharmacy staff can also perform some simple medical evaluations such as blood pressure readings or blood glucose tests. In the Russian Federation, these activities are not the main tasks of pharmacies and patients generally go to medical institutions for these purposes. The geographical network of outpatient polyclinics provides an opportunity to do this quite easily.

13.7.7 Medicines Use Research (Including Drug Utilization Evaluation [DUE] Research)

Formal accountability for the monitoring of compliance with procedures of disposal of drugs occurs and is the responsibility of the healthcare service. These are conducted regularly with "case for" verification. As previously described, optimal utilization of medicines is done through according to standards and procedures listed by Roszdravnadzor. At the same time, a number of hospitals (mainly large hospitals owned and sponsored by corporations) have "clinical pharmacists" responsible for advising GPs about the most effective use of medicines. It is also the case that sometimes a single clinical pharmacy specialist serves a number of medical institutions.

13.8 Conclusions: Summary and Way Forward

This chapter has outlined the current status of pharmaceutical policy and practice within the context of the Russian Federation. There has been significant change over recent years in Russia and this chapter highlights the progress that has been made. An effective system of assessment and use of medicines, which aims to reduce cost

and support local manufacturers, has been established in the Russian Federation. At the same time, there are limitations and areas to work on. The system does not take cost-effectiveness factors into consideration when selecting medicines due to the inability to increase the healthcare budget. Inclusion of new medications into federal and regional healthcare programs results in the need to withdraw or reduce the share of other medicines and other healthcare expenses as well (due to the joint healthcare programs budgets). Discrepancy between the fixed budget and cost-effectiveness models of HTA has probably caused delays in the creation of a comprehensive HTA system. Current elements of HTA exist in the format of legal requirements. For example, cost-effectiveness and budget impact data need to be presented in a submission dossier for EDL inclusion. There is also a dearth of information which evaluates the service provision within pharmacy and the optimal use of medicines through Drug Utilization Evaluation (DUE) research. As such medicines use evaluation is a significant area of future research in the Russian Federation.

The heterogeneous market of medical services in Russia and the complex levels of decision making require a multilevel HTA based system capable of providing expertise at the federal and regional levels and at the agencies, depending on funding and specific challenges. The important elements of HTA relevant to the market have not been assembled within the system, ensuring the satisfaction of these needs. There is a legislative requirement for "cost-effectiveness analyses" in the dossier for inclusion of drugs in Essential Drug List (EDL) but this requirement does not impact on the final decision. Health economic analyses are a part of the responsibilities of the expert Council at The Federal Agency for Research Organizations (FANO) along with horizon scanning and market access for locally developed innovative medicines. There are a number of other institutions which have not been involved in the health-economic arena before but can take part in those activities in the future. In the near future, we can expect the structuring of the HTA system as well as defining of formal structures responsible for clinical-economic analysis, assessment of the quality of this analysis, identification of needs, and development of an effective and transparent procedure of decision making.

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