Analysis of Barriers to Innovation in Healthcare Sector of the Russian Federation and Suggested Proposals for their Mitigation

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ABSTRACT

The article is devoted to the analysis of barriers to the introduction of innovations in the health care of the Russian Federation and the development of proposals for their mitigation. The author justifies the relevance and significance of the topic of study. The following groups of barriers to innovation in the healthcare of the Russian Federation are considered: barriers to the use and produce innovative medicines, barriers to innovative medical equipment and reagents, barriers to apply information and communication technologies, barriers to the protection of intellectual property. It is concluded that these obstacles hinder the introduction into the Russian market and the use of innovative medicines, medical equipment, as well as the full use of information and communication capabilities. All these reduce the availability of high-quality medical care to the general population of the country. The proposals made by the author aimed at mitigating and eliminating the identified barriers and minimizing the consequences of their impact. It is emphasized that in the future, concept statements specification and bringing them to the level of structured integrated practical solutions with financial and economic justifications are required.

Key Words: *Innovation, Health care, Medicines, Medical equipment, Intellectual property, Information and communication technologies*

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INTRODUCTION

Access to advanced medical technologies and therapies is a precondition to comprehensively and effectively ensure the constitutional right of Russian citizens for health protection and medical care. Modern medical advances are characterized by newly developed drugs enabling continuation maintenance therapy and complete elimination of some previously incurable diseases [1]. At the same time, diagnostic methods are developing, which help to detect serious diseases more efficiently in the early stages, as well as to profile patients genetically and enhance treatment success [2, 3]. The introduction of innovative medicines and medical equipment to the Russian market may be delayed due to regulatory and financial barriers [4]. To eliminate regulatory barriers, legal framework improvement is primarily required. Financial barriers cannot be completely removed due to the limited financial resources allocated to the health care sector. In this regard, it is crucial to develop approaches to financial resource priority, primarily based on the purchased drug, chemical, and apparatus clinical efficacy.

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Public money should be primarily spent on innovations that save human lives and increase life expectancy, taking into account its quality.

Many issues related to the introduction of innovation in the health care sector are well studied in domestic and foreign literature. Criterion methods to assess drug innovativeness are considered in the scientific article "A Review of the Existing Foreign Approaches to Determine and Assess Drug Innovativeness" [5]. The challenges to assess therapy effectiveness are analyzed in detail in the work "Approaches to Single Methodology Formation to Calculate Incremental “Costs/Effectiveness” indicators applying the example of antitumor drugs as part of the revised lists of drugs for medical use" [6]. Approaches to determine the thresholds of willingness to pay for making decisions on financing healthcare technologies are highlighted in the work "Potential Methods to Determine the Thresholds of Willingness to Pay for Making Decisions on Financing Healthcare Technologies out of Public Funds" [7]. An example of the works that address health care sector fundraising is the monograph "Health Insurance and Peculiarities of National Health Insurance Systems" [8].

Besides, foreign literature offers comprehensive data to assess the clinical and cost-effectiveness of various technologies introduced in the healthcare sector. The data used in the study reflects common approaches to cost efficiency assessment [9] and approaches to assess the efficiency used in the countries selected [10, 11]. A separate body of literature is presented by studies assessing the impact on healthcare efficiency and the role of specific technologies. Examples include publications that assess telemedicine cost-effectiveness [12, 13], assess an integrated approach to treat back diseases [14] and examine the impact of digital technologies on healthcare efficiency [15]. In general, it can be stated that approaches to criterion-based assessment and provability of innovation cost-effectiveness are well known and studied. In this regard, in the framework of the current study, it was crucial to supplement theoretical knowledge with information on the current practice to introduce innovations in Russia, in particular, to reveal the things preventing the introduction of innovative drugs, substances, and equipment with already proven positive effects.

MATERIALS AND METHODS

In the research work of the Russian Academy of National Economy and Public Administration under the President of the Russian Federation, the main barriers to the introduce innovation in the health care sector of the Russian Federation were analyzed and systematized.

In addition to the reviewed scientific literature, the information base of the study also included specialized materials published in the publicly available source (Vedomosti, Kommersant, RBC, Vademecum & others), as well as Internet websites with a list of regulatory documents governing relations in the health sector (the Consultant Plus base, the Garant information system).

An anonymous expert survey, involving practicing physicians, heads of health centers, patient organizations, representatives of Russian and foreign pharmaceutical companies, manufacturers and importers of medical equipment, was used as the main method of the research, along with the literature and open-source material study.

RESULTS AND DISCUSSION

1. Barriers to Use and Produce Innovative Medicines

In Russian legislation, there is no criterion definition for innovative drugs, as a result of which they are subject to the same regulatory environment as other drugs. The N 61-FL Federal Law "On the Circulation of Medicines" of 12.04.2010 gives special wording for "original" medicines, but the concepts of originality and innovativeness are not identical. Since innovative drugs are not regularly allocated, statutory regulation is applied to them on a general basis, and the possibilities to implement specific public procurement approaches are minimal. Another effect of the lack of a definition for innovativeness is the difficulty to motivate innovative developments in Russia since the mechanisms to support domestic manufacturers do not draw a clear line between the creation and production of new generics and original innovative drugs. In this regard, it seems to be reasonable to introduce the concept of an innovative drug into the regulatory framework, primarily using the criteria for therapeutic innovation, which are given in the N 871 Decree of the Government of the Russian Federation of 28.08.2014.

One of the most serious barriers to drug introduction into the Russian market is the requirement of mandatory clinical trials in the country as part of the authorization procedure, as a result of which, according to expert estimates, new drug introduction to the market may be delayed by at least 2-3 years. For example, Sofosbuvir was registered in Russia only 2-2.5 years after its introduction into the US and EU markets. There are no genetic, physiological, and therapeutic justifications for such requirement due to the heterogeneity of the Russian population, as well as people involved in clinical trials abroad. China, the population of which is genetically far more distinct from the European population, has abandoned a similar norm.

In 2014, the Federal Law "On Medical Product Circulation" was amended, according to which the results of clinical studies conducted outside the Russian Federation regarding orphan drugs began to be recognized in the Russian Federation. It seems reasonable to remove regulatory restrictions on the recognition of clinical trials in the countries strictly regulating drugs according to the

WHO list. Drugs not registered in Russia could be marked with a special inscription informing that the drug was registered only in the EU, the USA, Japan, or other jurisdictions.

The vast majority of innovative drugs are expensive. Therefore, for patients in Russia, this drug availability depends on whether drugs will be purchased by the state. Unlike most countries, there is a public procurement system operating in the health sector of the Russian Federation, instead of a treatment cost compensation system. According to many experts, the approach adopted in Russia is initially less patient-oriented. Current practice analysis reveals several vulnerabilities in the public procurement system.

Firstly, the existing regulatory framework poorly regulates prioritization of medical center applications to supply drugs of various nosologies and prioritization of medical center applications to supply drugs of the same nosology. Therefore, when forming the list of auctions and making decisions on budget allocation, subjective factors gain a key role. Some applications can be rejected on formal grounds only if, for example, application rules are violated, although as a result of such decisions, some nosologies may lose the required drug supply. Being more expensive, innovative medicines are in an unwinnable situation, since the budget-saving factor comes into the picture when there are no prioritization criteria.

Secondly, financing to purchase the most expensive authorized medicine often falls into the format of manual control. The experience of bringing the innovative drug SPINRAZA to the Russian market to treat spinal muscular atrophy revealed the issue of the lack of criteria based on which funding sources can be determined. Since SPINRAZA finance was not provided by federal programs, the purchase of the drug after its authorization was automatically assigned to the budgets of the entities of the federation following Federal Law No. 323, which establishes the right of citizens to have authorized medicines. However, due to the high drug cost, the entities of the federation avoided buying it, which led to a large number of trials, including trials in the European Court of Human Rights. Forcing regions to purchase expensive drugs like SPINRAZA may lead to a shortage of funds to purchase simpler, but widely used drugs or medical equipment.

It seems reasonable to include expensive drugs in special federal programs, such as a high-cost nosology program. The effect will involve not only an increased drug availability due to better federal budget capabilities but the reduced cost as a result of economies of scale as well, since the volume of batches purchased centrally will be higher than that of the regional purchases. Attempts in this area are being made. On October 28, 2020, Prime Minister M.V. Mishustin issued an order to establish a federal center for citizens' drug supply, which will deal with the purchase of medicines under federal programs.

In countries with advanced medicine, the challenge of procurement prioritization is dealt with based on criteria for medicine clinical effectiveness. The basis for such a criterion assessment can be the QALY (quality-adjusted life years) indicator, which determines the number of years of life adjusted for quality due to drug administration. QALY can be compared with the drug cost. Accordingly, preference is given to drugs with a better cost-effectiveness ratio.

To exclude ultra-expensive drugs from public funding, a willingness-to-pay threshold indicator is usually applied, which is calculated as the therapy cost limit relative to a year of quality life. In the legislation of the Russian Federation, unlike many countries with developed medicine, there is no such a concept introduced currently, as a result of which ultra-expensive drugs can be purchased, while cheaper and more effective ones may not be purchased.

A developed and legitimized methodology to assess the willingness to pay will lead to the fact that the drugs with a reduced threshold of willingness to pay will remain in the system of regional public procurement, taking into account limited budget funds, and the federal program system will include drugs with a higher threshold of willingness to pay. Drugs that exceed the threshold of willingness to pay will not be purchased, like these are purchased in the countries with advanced medicine. On the one hand, this can deprive some patients of the treatment required. But, on the other hand, with the same resources spent, the number of saved lives will increase, that is, public money will be spent more fairly. Thus, once competently studied, the introduction of the threshold of willingness to pay will not create an additional barrier for patients; on the contrary, it will remove barriers to purchasing the most important drugs producing ultimate benefits to society and people's lives.

Thirdly, the existing regulatory framework and public procurement practice does not imply long-term procurement guarantees, which produces several negative effects on the market of innovative drugs. Patients do not have any guarantees to have long-term therapy with certain drug administration. There are cases when the therapy is not completed but a drug is replaced with another one due to procurement cessation, causing unpredictable outcomes for the patient. On the other hand, due to the lack of sales guarantees, such practice is a negative incentive against localized production of innovative drugs in Russia. In this regard, it seems reasonable to improve the public procurement system by expanding contractual mechanisms.

The first step may involve the introduction of procurement law by trade names for 5 drug groups, the replacement of which is considered unacceptable within a single INN

(International Nonproprietary Name for Pharmaceutical Substances) when treating a patient:

- biotechnologically produced drugs;
- narrow therapeutic index drug;
- natural or chemically synthesized drugs with high molecular weight compounds with different molecular weight and/or structure;
- donor blood or plasma-derived drugs;
- drugs produced using specific delivery methods.

In the future, it is reasonable to develop the legal framework and practice for alternative procurement mechanisms, including negotiation and conciliation mechanism development; withdrawing patented drugs from the public procurement system and procuring some drugs via government contracts over the patent duration; applying lengthy agreements, special investment contracts, offset transactions; developing risk-sharing models, including pay-as-you-go agreements.

Fourthly, the system of preferences for domestic producers needs to be improved. The main support tools are a "third is a crowd" rule, which implies a ban on tender participation for foreign manufacturers if two or more domestic manufacturers bid to purchase drugs with a certain actual substance, and a decreasing coefficient system (15% for medicines, 25% for substances), which provides for a reduced cost of goods when concluding a contract in case imported drugs win in monolots (from countries outside the EAEU), under the conditions that Russian suppliers participate in the same monolots.

Sometimes, the "third is a crowd" rule limits patients' access to the imported drugs needed, instead of which domestic generics of lower and sometimes dubious quality are purchased. As a result, in 2020, the Ministry of Health removed 9 drugs (anti-cancer drugs mainly) from the "third is a crowd" rule.

A flexible approach seems to be the most optimal approach when the "third is a crowd" rule can be used for auctions to purchase simple non-innovative drugs with already approved manufacture in Russia with no loss of quality for patients. This measure will protect Russian patients and manufacturers from the numerous cheap and not always safe generics produced in some Asian countries. For more complex drugs, when the quality of Russian generics is challenged, or drugs whose replacement within the same MNN is unacceptable, the "third is a crowd" rule is advisable to cancel.

2. Access Barriers to Innovative Medical Equipment and Reagents

As with medicines, one of the main barriers to introduce medical equipment into the Russian market is the complexity of the authorization procedure, which also entails high costs for manufacturers. After the No. 1416 Decree of the Government of the Russian Federation of 27.12.2012 came into force, the number of authorized medical devices decreased by several times. According to expert estimates, due to authorization complexity and high costs, the launch of innovative products is delayed by 2-3 years on the Russian market.

Another challenge is the authorization fragmentation: diagnostic systems are usually not authorized as a whole - apparatus, reagents, and control materials are authorized separately. In some cases, the use of apparatus may be virtually impossible due to the lack of authorized reagents for their operation. For example, oncologists face the problem of non-authorized imported reagents (having no Russian analogues) aimed to genetically profile cancer patients, while genetic sequencers can have authorization.

It is required to design solutions to remove authorization barriers in the following areas: recognition of medical apparatus testing conducted in countries with strict regulation; authorization procedure simplification, removing excessive bureaucratic authorization requirements; ensuring complex diagnostic system authorization; in exceptional cases, admission of the most important reagents with no authorization as a medical product.

As a rule, medical equipment is supplied to a medical organization in the acquisition terms. But due to frequent violations of operating and service rules, the use of unlicensed software products, expensive equipment can fail far earlier than its depreciation period. The situation is aggravated by the lack of restrictions prescribed by the legislation for poor-quality and untimely repair work. The use of life cycle contracts and leasing schemes is a perspective solution; however, restrictions have also been identified regarding the use of these contract forms.

According to data available, life cycle contracts are applied in Moscow only. The main challenges are related to the lack of guarantees for long-term budget financing (particularly under currency volatility conditions) and the complexity to "pack" separately authorized equipment, reagents, control apparatus, etc. into a single contract.

Leasing schemes are widely and successfully used by private clinics (dental clinics in particular), but leasing is less accessible to public clinics due to the impossibility to finance them from budget funds and due to limited financing from the compulsory medical insurance system in the amount exceeding 100 thousand rubles. It seems reasonable to develop a regulatory framework that removes or mitigates these limitations.

3. Barriers to Apply Information and Communication Technologies

Emerging information technologies can potentially and dramatically improve the quality of diagnosis of several diseases and significantly simplify the processes of data

exchange between medical organizations, which will save time and reduce costs.

Telemedicine is one of the fastest-growing segments. Concerning telemedicine, the main barrier is a statutory prohibition to diagnose remotely, although medical community representatives note that in modern conditions, remote advisory for many disease types can be carried out with no quality reduction.

At the federal level, the issue of a doctor-to-doctor and a patient-to-doctor rate inclusion into the tariff system of telemedicine services has not yet been solved, regarding manipulations made using medically certified equipment and the cost of data being transmitted through communication channels with the required personal data protection. Of great importance and replication is the experience in charging telemedicine services in some regions (for example, Sverdlovsk and Sakhalin regions), where telemedicine is actively developing. The impact of the included telemedicine services in the compulsory medical insurance system on the workload of doctors, as well as the level of financial support for these services from the existing insurance premium volume, needs to be further assessed.

Professional standards aimed to ensure the quality of remote medical advisory are not sufficiently developed. A complementary study of legal issues regarding responsibility for transmitted data reliability is required, based on which decisions are made by doctors consulting remotely. Remote consultation regulation aimed to assign or adjust therapy for patients is poorly developed. As a result, the patient's face-to-face examination is usually required to prescribe medicine, which is extremely burdensome and may result in long travels to other regions. Similarly, the patient's face-to-face examination is usually required when issuing sick leaves.

The issue of personal data transfer and protection is acute. In many remote areas, not only databases and data transmission channels are missing that guarantee compliance with personal data protection standards established by the 187 Federal Law "On Security of Critical Information Infrastructure," but also there is no stable internet signal as well.

Currently, at the federal and regional levels in Russia, medical information systems are being created aimed to collect, store, transfer, and process patient records. On the one hand, at the regulatory level, the complexity of software authorization procedure is distinguished, but, on the other hand, the lack of unified standards to create such information systems is noted as well.

The lack of a unified comprehensive concept throughout the country, a single customer, unified approaches to technical assignments for software product design, and the fractioned nature of funding lead to the fact that regional information systems often turn out to be poorly compatible with each other, as well as with the federal Uniform State Health Information System. The optimal solution is to assign a federal authorized body to act as a single customer, which will ensure technical assignment unification for competitive procedures. Requirements for standardization of information systems can be drawn up in the form of a special subordinate act, like a government decree.

A particular issue is to determine the legal status of medical applications used in gadgets and the Internet of medical things, which imposes restrictions on their use. Criteria should be developed for when applications should be registered as medical products and when there is no need to register them as medical products depending on their functions.

4. Intellectual Property Protection Issues

An expert survey showed that the issue of intellectual property protection remains acute in Russia. Experts referred to the precedents when Russian courts recognized the legitimacy of generic drug production, introduction into the market, and engagement in procurement procedures in violation of the rights of patent holders. The prevalence of unlicensed software use, sometimes blowing out expensive equipment, was also noted. Many potential suppliers and investors are frightened by the FAS proposal for compulsory medicine licensing, which, in our opinion, can be applied only in extraordinary circumstances. In general, systematic effort to develop the legal framework aimed to solve intellectual property protection issues are required, including toughen sanctions against violators and improved law enforcement practices.

CONCLUSION

The study identified and systematized numerous regulatory barriers and gaps in legislation hampering the introduction and the use of innovative medicines, medical equipment to the Russian market, as well as the full use of information and communication capabilities, which ultimately reduces the availability of qualified medical care to the broad public. Concept statements were also suggested regarding the key efforts to mitigate and eliminate the identified barriers. In the future, concept statement specification and bringing them to the level of structured integrated practical solutions with financial and economic justifications are required.

It is hoped that the Federal Center for Planning and Organizing Drug Supply for Citizens will become one of the positive examples of a particularly practical solution; the order to establish it was signed by the Chairman of the Government when the material was being prepared to be published. The center establishment completely coincides with one of the study conclusions on the need to centralize expensive innovative medicine funding at the expense of

the federal budget, to purchase which, the regional budgets is not enough.

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