

Russian Healthcare System Overview



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Contents:

Introduction	3
Part 1 Public Healthcare System	
1.1 Legal Background and Priorities.....	6
1.1.1 Federal Legislation	6
1.1.1.1 Constitution of the Russian Federation.....	6
1.1.1.2 Fundamentals of the Russian Legislation on Citizens' Health Protection ...	6
1.1.1.3 National Project "Health"	7
1.1.1.4 Healthcare Development Concept until 2020	7
1.1.1.5 Guarantee Package of Medical Services	9
1.1.1.6 Other Federal Legislation	10
1.1.2 Regional Legislation in St. Petersburg	10
1.2 Organization structure	12
1.2.1 The Ministry of Healthcare and Social Development.....	14
1.2.2 Departmental system.....	15
1.2.3 Other Federal Healthcare organizations.....	15
1.2.4 Regional Level.....	16
1.2.5 Local (municipal) Level.....	16
1.3 Financing System.....	17
1.3.1 Mandatory Medical Insurance (OMS).....	18
1.3.2 How Healthcare Facilities are Financed?	20
1.4 Public Procurement	21
Part 2 Private Healthcare System	
2.1 General Overview.....	25
2.2 Private Healthcare Providers and OMS System.....	27
2.3 Voluntary Medical Insurance (DMS).....	28
2.4 Certification, Licensing and Registration Procedures	31
2.4.1 Medical Equipment, Instruments and Materials.....	31
2.4.2 Pharmaceutical Products and Services	34
2.4.3 Medical Activity.....	37
Part 3 Swedish Experience of Doing Business in Russia	39
Conclusions: Trends and Recommendations for Further Study	43
References	49
List of contacts	52
Appendix 1 Organization Structure of the Healthcare system in Russia	57
Appendix 2 Financing of Healthcare services in Russia (based on the Healthcare Development Concept until 2020)	58
Appendix 3 List of Documents for Registration of Medical Devices and Equipment	59
Appendix 4 List of Documents for Registration of Foreign Drug Agents.....	60

INTRODUCTION

Russian healthcare system has radically changed since 90s. Government initiatives to reform healthcare system and to open up the economy have caused a rapid growth in the Russian healthcare industry. There have been essential changes in legislation. The Russian Constitution provided all citizens right to free healthcare under Mandatory Medical Insurance in 1996. After a number of federal and regional laws which have transformed Russian healthcare system, the government is still working on other healthcare policy documents with emphasis on high technology, greater primary care, measures to combat high mortality rate, construction of cardiology centers and transition to insurance-based healthcare.

In 2006, a national project "Health" was launched to improve the country's healthcare system through improved funding and healthcare infrastructure. This plan not only helps to equip hospitals and clinics with advanced, high-end equipment and ambulance systems, build new medical centers, as well as launch nation-wide vaccination programs and free health checks but also opens new possibilities for private-public cooperation including foreign participants. The government has been working on developing of international cooperation on healthcare issues by establishing new rules for medical technology and devices market and enhancing the role of information management in healthcare system. The Russian healthcare system meets new challenges and opportunities which require in-depth analysis.

This study is based on general overview of Russian healthcare system at the present stage, including St. Petersburg case-study. Its main **objective** is to provide a general overview of the Russian healthcare system on the current stage as well as to analyze the main trends for its development in order to make a fundamental background for further specialized studies.

Targets:

- To give a general overview of legislation basis of the Russian healthcare system
- To analyze the decision making process at different levels within the Russian healthcare system and to provide a brief introduction to the Russian administrative environment with focus on the federal and regional government structures in St. Petersburg
- To analyze the main trends in the development of the Russian healthcare system
- To analyze financing flows in the public and private healthcare, including the role of mandatory and voluntary insurance systems
- To indicate the challenges facing by the private healthcare providers as well as the role of private sector in the Russian healthcare system
- To describe registration, certification and licensing procedures as obligatory stages to enter the Russian healthcare market
- To find the main differences in healthcare issues between St. Petersburg and other Russian regions
- To summarize the experience of Swedish companies which have entered the Russian healthcare market and to work out recommendations containing practical advices concerned to healthcare business in Russia
- To make suggestions for the further studies

Sources

The research is based on various sources of information:

- Laws, concepts of development, instructions of federal, regional and municipal levels of the Russian healthcare system
- Interviews
- Analytical statistics concerned to main figures of the Russian healthcare system
- Data from Russian research centers (analytical articles concerned to current stage of the Russian healthcare system)
- Data from official web sites of the Russian healthcare institutions
- Etc.

The Stockholm Region office in St. Petersburg has carried out 13 interviews with the representatives of government, public and private healthcare sectors in Russia:

- Agneta Ekblad, Development Director Eastern Europe, Carmel Pharma AB
- Alexander Golyshev, Chief Doctor of the Children's Clinical Hospital №5 named after N.F. Filatov,
- Alexander Mironenko, Head of St. Petersburg Regional Branch of All Russian Medical Association, Deputy Director of the St. Petersburg Institute of Ear, Throat, Nose and Speech, Honored Doctor of the Russian Federation, MD, professor
- Christoph C. Dengler, Lawyer and Translator for Russian, Mannheimer Swartling, heading the Pharmaceutical Group Russia
- Evgeny Mironenko, General Director of The Center of the medical and technical tests by R.R. Vreden (Medical Equipment Certification)
- Igor Akulin, Director of SOGAZ Insurance Group, Deputy Head of Medical Center SOGAZ, MD, lawyer
- Irina Mayorova, Board Member of the Regional Association of Healthcare Managers
- Irina Sandin, Business Development Manager, Elekta Ltd
- Larisa Petrenko, General Director of the Non-profit partnership for the development of the healthcare system "Professional Medicine", Representative of Global Hospital in St. Petersburg, Doctor of Higher Category, PhD
- Nadezhda Alekseeva, Chairman of the Association of Private Clinics, Director of CardioClinic
- Natalia Mironova, General Director of Swedish Dental network of clinics
- Oleg Sergeev, Chairman of the Permanent Committee on Healthcare and Environment of the St. Petersburg Legislative Assembly
- Roman Micaelyan, General Director of Arzumanov Consulting (Medical Licensing)

The survey is divided into 3 parts. The first part describes the public healthcare system including legal background, development strategies and organization structure, financing flows, mandatory medical insurance system and public procurement. The

second part is devoted to the private healthcare providers including their participation in mandatory and voluntary medical insurance systems, as well as certification, registration and licensing procedures. The third part contains recommendations to the companies based on Swedish experience of entering the Russian market.

PART 1 PUBLIC HEALTHCARE SYSTEM

1.1 Legal Background

The legal basis for health care reforms at the federal level is provided by a variety of legislative acts (Codes, Federal laws), Presidential decrees, Decisions and Proposals of the Government of the Russian Federation, and Orders of the Government and of the Ministry of Health and other ministries. The legal basis at the regional level is provided by legislative instruments enacted by the governments of the subjects of Russian Federation. The most important instruments are listed below; it should be stressed that this list is not exhaustive.

1.1.1 Federal Legislation in the Healthcare Sector

1.1.1.1 Constitution of the Russian Federation

The Constitution of the Russian Federation was adopted at national voting on 12 December 1993. It contains two articles related to the healthcare system:

Article 7:

1. The Russian Federation is a social state whose policy is aimed at creating conditions for a worthy life and a free development of man.
2. In the Russian Federation the labor and health of people shall be protected, a guaranteed minimum wages and salaries shall be established, state support ensured to the family, maternity, paternity and childhood, to disabled persons and the elderly, the system of social services developed, state pensions, allowances and other social security guarantees shall be established.

Article 41

1. Everyone shall have the right to health protection and medical aid. Medical aid in state and municipal health establishments shall be rendered to individuals gratis, at the expense of the corresponding budget, insurance contributions, and other proceeds.
2. In the Russian Federation federal programmes of protecting and strengthening the health of the population shall be financed by the State; measures shall be adopted to develop state, municipal and private health services; activities shall be promoted which facilitate the strengthening of health, the development of physical culture and sport, ecological and sanitary-epidemiological well-being.
3. The concealment by officials of the facts and circumstances posing a threat to the life and health of people shall entail responsibility according to the federal law.

As you can see the main law inherited the guarantee of free healthcare services to population. It is also very important to stress that it stipulated equal rights of public and private healthcare which is sometimes missing in other legislation acts.

1.1.1.2 Fundamentals of the Russian legislation on citizens' health protection (1993)

The goals of Russian Federation legislation on citizens' health protection is:

- to determine the responsibility and competence of the Russian Federation, subjects of the Russian Federation towards the issues of citizens' health protection according to the Constitution of the Russian Federation and federal laws, also to determine the responsibility and competence of local governments towards the issues about citizens' health protection.

The law regulates the citizens' health protection sphere, enterprise activities, other institutions and organizations not depending on the form of property and also state,

municipal and private systems of healthcare. It also determines citizens' rights in the healthcare sphere and sets up guarantees of their accomplishment; determines the professional rights, duties and responsibilities of medical and pharmaceutical workers, and sets up guarantees of their social support.

When appealing to the medical aid and getting it, the patient has a right for:

- choosing a doctor, including a general practitioner (family doctor) and attending medical doctor, taking into account his/her agreement, and also choosing a medical-preventive institution in compliance with the agreements of mandatory and voluntary medical insurance.
- keeping in secret the information about the fact of applying for medical aid, about the health condition, diagnosis and other information, that was got during his/her examination and treatment, according to the clause 61 of original Bases.

Medical aid can be provided in the medical institutions, including those of them that have been established by natural persons, not depending from the form of property, the organization-legislative form and departmental subordination, that has got license for medical activities. Medical aid can be also offered by individuals, providing private medical practice, if they have license for medical activities.

1.1.1.3 National Project "Health"

In 2006 a national project 'Health' was launched to improve the country's healthcare system through improved funding and healthcare infrastructure. This plan helped equip hospitals and clinics with advanced, high-end equipment and ambulance systems, build new medical centers, as well as launch nation-wide vaccination programs and free health checks. The project has also been working on developing medical technology market through initiatives to blend healthcare and information technology. One of the focuses was made on salary increase of medical staff working in the primary care as well as their wider training programmes.

The project was initiated by the Russian President Vladimir Putin and coordinated by the President Office. It was mostly financed by the federal budget. However regional and municipal levels have also contributed a lot to the financing of the programme. In 2006 the budget of the programme was 78,98 billion RUR, while the total budget for 2007-2009 was 346,3 billion RUR.¹

In general the Health project received very positive remarks in the society. The industry has benefited from the government's 'National Health Program', which provides substantial funds to build 15 specialized health centers in the country. This higher purchasing power of hospitals and active government support has also assisted the medical devices market.² However some experts wrote that taking into consideration the level of financing better results especially in the field of primary care development could be reached.

1.1.1.4 Healthcare Development Concept 2020³

The new legislation goes beyond the traditional focus on health-care delivery to include a concern about population health, setting out the goals of reducing mortality in working ages, especially by lowering rates of injuries and alcohol poisoning, as well as reducing infant and maternal mortality. It also highlights the need for effective action against

¹ Official website of the programme http://rost.ru/projects/health/health_main.shtml

² Frost & Sullivan's report "Political and Policy Analysis for the Russian Healthcare Industry"(2009)

³ The official website of the concept is <http://www.zdravo2020.ru/>

“socially determined conditions” such as drug addictions, smoking, hazardous drinking, sexually transmitted diseases, tuberculosis, and AIDS.

The Russian government made emphasis on high technology, greater primary care, reduction of hospital capacity, improvement of management, introduction of new systems of payment for facilities and individual providers of services, construction of cardiology centers and transition to insurance-based healthcare.

The major priorities for reform include closing the gap between formal commitments to the population and available resources; shifting the structure of provision towards greater reliance on integrated primary care; adopting payment schemes in the healthcare sector that encourage more cost-effective therapeutic choices; and modernizing the system of mandatory medical insurance.

The objectives of the concept are:

- population growth up to 145 million people;
- increase of life expectancy to 75 years
- decrease of infant mortality to 7,5 per 1000 born (20% decrease compared to 2007)
- decrease of maternal mortality to 18.6 per 100 000 born (15.7% decrease compared to 2007)
- formation of healthy lifestyle, incl. curtailment of tobacco and alcohol demand
- improvement of quality and accessibility of healthcare services, guaranteed to the population of the Russian Federation
- The goals of the concept are:
 - Creation of conditions, possibilities and motivation of population for healthy lifestyle
 - Development of the healthcare system
 - Specification of state guarantees of free medical services provision to the population
 - Improvement of pharmaceutical supply at the outpatient departments within the frames of the OMS system
 - Creation of an effective management model of financial resources of the state guarantee programme
 - Further training of medical staff and creation of motivation system for quality work
 - Development of medical science and innovations in the healthcare sector
 - IT development in healthcare

One of the most interesting statements in the concept is the ambition of the government to increase the size of insurance premiums to the Mandatory medical insurance system (OMS) both for working, and the non-working population as well as transfer to a single-channel financing model (via OMS). Then tariffs for the medical care should include all expense items connected with maintenance of activity of corresponding healthcare facilities.

With introduction of single-channel financing model the insurance medical organizations will become ‘buyers’ of medical services signing contracts on purchasing medical

services with the medical organizations of various organization-legal forms and pattern of ownership. (see How Healthcare Facilities are Financed?).

1.1.1.5 Guarantee Package of Medical Services

The free medical care and pharmaceuticals as stipulated by the Guaranteed Package Programme are listed below (by source of finance):

Free services to be covered by government budgets:

- urgent medical care
- ambulatory, polyclinic and hospital care provided to patients with socially significant diseases, including:
 - o skin and venereal diseases
 - o tuberculosis
 - o AIDS
 - o mental problems
 - o drug addiction
 - o pregnancy and delivery abnormalities
 - o some types of conditions of children and infants
- dispensaries monitoring healthy children
- specialized pharmaceutical care and prostheses
- some types of expensive medical care.

Free services to be covered by the mandatory medical insurance funds:

- ambulatory, polyclinic and hospital care provided to patients with:
 - o contagious and parasitic diseases, excluding venereal diseases, tuberculosis and AIDS
 - o cancer, endocrine system diseases, skin diseases
 - o nutrition abnormalities, nervous system diseases
 - o blood diseases, immune system pathology, heart and circulatory diseases
 - o eye, ear and respiratory diseases
 - o digestive system pathology, all types of injuries and poisonings
 - o bone and muscle diseases
 - o some types of inborn adult pathology
 - o some other diseases.

Per capita indexes, defining health care costs per person, are to be developed by regional authorities using federally determined methodology.

There are also services which are explicitly excluded from the guaranteed package:

- cosmetic surgery;
- homeopathic, alternative, or 'non-professional' therapies offered by practitioners with no medical qualification;

- dental services except basic provision for children, veterans and other special groups;
- medical prostheses including dentures (except for veterans and other special groups);
- rehabilitation or convalescence in institutions other than those approved by the Ministry of Health and Social Development ;
- educational activities and health promotion literature from non-Ministry of Health-approved health centers training in emergency procedures and nursing;
- pharmaceuticals for outpatients.

1.1.1.6 Other Federal Legislation

For more information about legislation on OMS, licensing, registration etc. see resp. chapters.

Regulation on labour relations in the healthcare and other relations directly connected to them according to the Constitution of the Russian Federation, and federal constitutional laws is provided by Working law, Employment laws, Labour legislation (including Work safety legislation) consisting of the Labour Code, other federal orders and the laws of subjects of the Russian Federation. The issues of working environment, medical waste management etc. are regulated by Labour Code, Manual of the Ministry of Health and Social Development on Hygienic Criteria for Evaluation and Classification of Labour conditions, Federal Law On Production and Consumption Wastes, Federal Law on Technical Regulations and other legal acts of the federal and regional level.

Until the end of 2010 the Russian Ministry of Health and Social Security is going to introduce a number of bills to the Russian Duma, in particular about biomedical technologies, a new bill on the Health Protection of the Citizens and a bill on Protection of Rights of Patients. This year a new bill on Mandatory Medical Insurance is planned to be introduced, which will include measures on transfer to one-channel insurance system.

1.1.2 Regional Legislation in St. Petersburg

The basic law in St. Petersburg is the Law on the Health Protection of the Citizens of St. Petersburg. It contains the main priorities of the healthcare development according to the federal legislation and in particular it stipulates the competences of the executive and legislative authorities.

Legislative Assembly of St. Petersburg has the following competences in health protection of citizens in St. Petersburg:

- To pass laws and other legal acts of St. Petersburg on health protection of citizens, including:
 - o the main directions of the city policy of St. Petersburg in health protection of citizens in St. Petersburg;
 - o approval of the special healthcare programmes of St. Petersburg;
 - o tax exemption, fees and other payments to the St. Petersburg city budget for organizations whose activities are aimed at protecting the health of citizens in St. Petersburg
- To provide control functions to ensure compliance with the laws of St. Petersburg and other legal acts adopted by the Legislative Assembly of St. Petersburg,

budget of St. Petersburg in part, provided financing for the health of citizens in St. Petersburg, including:

- the budget of St. Petersburg regarding spending on free pharmacological supply of the citizens of St. Petersburg;
- budget implementation of the Territorial Medical Insurance Fund of St. Petersburg;
- compliance with the laws of St. Petersburg and other legal acts adopted by the Legislative Assembly of St. Petersburg in the field of environmental protection, environmental safety and sanitary-epidemiological welfare of population.

The competence of the executive bodies of St. Petersburg (the government) in health protection of citizens in St. Petersburg is:

- to develop and implement city policies on health protection of citizens;
- to form a government public healthcare system of St. Petersburg;
- to ensure the development and logistical support of St. Petersburg public healthcare institutions and social protection institutions;
- to ensure and monitor the quality of healthcare to citizens in St. Petersburg;
- to coordinate the activities of public healthcare institutions of St. Petersburg;
- to assist development of municipal healthcare organizations in St. Petersburg;
- to develop special programmes for St. Petersburg in the field of health protection of citizens;
- to implement special programmes in the field of health protection of citizens in St. Petersburg;
- to provide information to the citizens on the health situation in St. Petersburg and the measures taken for its protection, as well as on the prevalence of socially significant diseases and diseases that pose a danger to others;
- to organize and coordinate the activities of the state educational institutions providing staff medical training;
- to organize the education of citizens in St. Petersburg in the field of health;
- to organize international cooperation of St. Petersburg in the field of health protection of citizens;

In 2004 The City of St. Petersburg has adopted a Concept of Healthcare System Modernization for 2004-2010. The objective of the concept is efficiency growth of the healthcare system and provision of quality and accessible healthcare services according to the following principles:

- Development of the joint regional policy of health maintenance
- Maintenance of the state healthcare system
- Assurance of balance in the development of all healthcare sectors: federal, city, district and private
- Strategic planning and sustainable development of the healthcare sector

The main priority of the concept is development of primary care with a focus on disease prevention and motivation of population for healthy lifestyle. Among other priorities are

development of inpatient departments, disease control and prevention among mothers and children, development of ambulance services, medical treatment of socially significant diseases, geriatric services, blood banking, diagnostics, healthcare management (incl. IT), medical insurance, pharmacological support, infrastructure and research.

The Concept also contains priorities for international cooperation:

- Primary care reform
- Microbiology and prevention of HIV, hepatitis, tuberculosis, HAI, alcohol, tobacco and drug abuse
- Further training of medical staff
- Closer cooperation with WHO in particular regarding therapeutic drug monitoring

Oleg Sergeev, Chairman of the Permanent Committee on Healthcare and Environment of the St. Petersburg Legislative Assembly:

St. Petersburg healthcare system as in the whole Russia needs modernization.

The City of St. Petersburg has also adopted an Activity Plan for the Implementation of the Health project in St. Petersburg. The document is rather general and has the same priorities as the national project “Health”, i.e.: primary healthcare development (incl. training of GPs, salary increase to the medical staff, provision of modern equipment to polyclinics), provision of transport for ambulances and emergency call services, prevention measures of HIV and hepatitis B and C, vaccination of the population and provision of hi-tech medical services.

St. Petersburg was one of the regions which has introduced a system of maternity certificates within the frames of the Health project. Maternity certificates have been issued to pregnant women since 1 January 2006. Based on this voucher, the government pays prenatal care centers and maternity hospitals for the services they provide to pregnant women. A pregnant woman can also choose a prenatal care provider and a maternity hospital, in this case a model when money follow a patient was introduced, which became a step forward in the healthcare system.

Alexander Mironenko, Head of St. Petersburg Regional Branch of All Russian Medical Association, Deputy Director of the St. Petersburg Institute of Ear, Throat, Nose and Speech, Honored Doctor of the Russian Federation:

St. Petersburg during a long time has been a pilot platform for many healthcare projects. It was in particular one of the first which introduces the OMS system.

1.2. Organization Structure

The Russian Federation is administratively divided into three levels: the federal, the regional – comprising 21 republics, 9 krajs, 46 oblasts, 5 autonomous entities and the cities of Moscow and St. Petersburg – and the municipal, consisting of rayons, cities, towns, villages and rural settlements. Depending on their size, cities may be divided into rayons or constitute a single rayon. The republics, krajs, oblasts, autonomous entities and the two cities of Moscow and St. Petersburg (also known as “Federal subjects”) are referred to as territories at the oblast or regional level.

The healthcare system follows the administrative structure of the country and is divided into federal, regional (oblast-level) and municipal (rayon-level) administrative levels. Please, see Appendix 1 Organization Structure of the Healthcare system in Russia.

Legislation entitled “Fundamentals of the Russian Federation legislation on citizens’ health protection” of 1993 defines the following as the responsibilities of the federal government:

- protection of human and citizen rights and freedoms in the area of health protection;
- elaboration of a federal policy to protect citizens’ health;
- elaboration and implementation of federal programmes on healthcare development, disease prevention, medical care delivery, public health education and other issues to protect citizens’ health;
- definition of the percentage of expenditures for healthcare within the federal budget; elaboration of a fiscal policy (including tax exemptions, duties and other payments to the budget) in relation to health protection;
- management of federal property used in health protection;
- establishment of a common federal statistics and accounting system in health protection;
- development of common criteria and federal education programmes for medical and pharmaceutical training, determination of a list of specialties in healthcare;
- establishment of medical care quality standards and control over compliance with them;
- development and approval of a basic programme of mandatory medical insurance and establishment of tariffs for its premiums;
- defining benefits for certain population groups receiving medical-social care and pharmaceutical supplies;
- organization of the State Sanitary Epidemiological Surveillance (SSES); development and approval of federal sanitary regulations, norms and hygienic standards; securing state-sanitary epidemiological surveillance; organization of the system for the sanitary protection of the RF territory;
- coordination of the activity of state and administrative authorities, sectors of the economy, and of the state, municipal and private healthcare systems;
- establishment of procedures for medical expertise;
- establishment of procedures for licensing of medical and pharmaceutical activity.

According to the same legislation, the regions’ responsibilities are defined to be the following:

- development and allocation of the regional budgets;
- material-technical supply for the healthcare facilities under the ownership of the region;
- approval of territorial compulsory health insurance programmes;
- establishment of additional benefits for certain population groups receiving medical-social care and pharmaceutical supplies;
- coordination of activity of state authorities, municipal and private healthcare systems’ subjects in the area of health protection;

- organization and coordination of training of health protection personnel;
- licensing of medical and pharmaceutical activity within the regions.

Finally the legislation stipulates the following responsibilities for the municipal (rayon) level:

- organization, maintenance and development of municipal healthcare facilities;
- securing the sanitary wellbeing of the population;
- development of the local budget for healthcare expenditures.

The municipal healthcare system includes local governmental departments, authorized to realize the managing process in the healthcare sphere, and also medical, pharmaceutical and drugstore organizations, placed as municipal property.

The legislation is vague concerning the precise delineation of responsibilities of the federal level toward the regional, as well as of the regional level toward the municipal.

1.2.1 The Ministry of Healthcare and Social Development

The Ministry of Healthcare and Social Development is the highest administrative level, headed by a minister appointed by the prime minister and approved by parliament. It is the central policy formulating body for the Russian Federation and retains nominal rights to oversee the work and decisions devolved to the regions. Its main official responsibilities include:

- developing and implementing state policy in healthcare;
- developing and implementing federal health programmes, including initiatives on diabetes, tuberculosis, health promotion, health education, disease prevention etc;
- developing draft legislation and presenting it to the State Duma;
- governance of federal medical facilities;
- medical education and manpower development;
- epidemiological and environmental health monitoring and health statistics;
- control of infectious diseases;
- development of health regulations;
- development of federal standards and recommendations for quality assurance;
- development and implementation of federal health programmes (TB, AIDS, health promotion, etc.);
- control and licensing of drugs.

The Ministry has 13 departments. The Department for International Collaboration is handling bilateral and multilateral collaboration with a large number of international organizations and countries.

There is a department within the Ministry which coordinates the distribution of quotes of hi-tech medical services. The department defines types of medical services, healthcare providers and number of patients in the regions who will get these services during the next year. The regional level then distributes the quotes among the patients in the region.

The budget of the Ministry also covers the expenses of research institutes, clinical activity of Russian Academy of Medical Sciences, research centers and medical training institutions. Federal medical facilities form about 4% of the total bed capacity in Russia.

One of the services coordinated by the Ministry of Health and Social Development, with a visible presence in the regions, is The Federal Service for Surveillance in the Field of Consumer Rights' Protection and Human Well-being (Rospotrebnadzor). It is responsible for public health issues like infectious disease control and registration of diseases, food safety, control of drinking water and several other issues. Its regional presence is maintained through Territorial Directorates located in all regions, funded over the federal budget. The Territorial Directorates have local offices at the municipal level, and representatives in hospitals reporting through their structures.

1.2.2 Departmental system

It consists of ministries other than the Ministry of Health and Social Development as well as public enterprises which traditionally have provided healthcare services exclusively for their respective employees and their families. The Ministries of Defense, Railways, River and Marine Transportation, Interior and many others have polyclinic networks and some also provide inpatient facilities.

These healthcare services are generally of superior quality. Funding usually comes from the federal budget via the Ministry of Finance. In the case of the military/security systems, funding is from a combination of the federal budget and extra-budgetary resources.

There is access to most of these services on a private basis, i.e. when a patient pays out-of-pocket or via voluntary (private) insurance; however, the very high cost of these services precludes broader access.⁴

1.2.3 Other Federal Healthcare organizations

Alexander Mironenko, Head of St. Petersburg Regional Branch of All Russian Medical Association, Deputy Director of the St. Petersburg Institute of Ear, Throat, Nose and Speech, Honored Doctor of the Russian Federation:

Other federal healthcare organizations in St. Petersburg can be divided into 2 groups:

- *R&D Institutes (the main goal is research, providing of medical services within the framework of the National project "Health", i.e. provision of hi-tech services upon the federal order.*
- *Educational organizations (institutes, universities). These organization also provide hi-tech medical services according to the quotes of the federal government.*

All federal organizations have a right to participate in the regional OMS programme if the Ministry allows them to use a number of beds for this purpose. The hospital signs an agreement with the regional Health Committee and receives reimbursement per patient from the OMS fund.

Russian Academy of Medical Sciences: with the independence of the Russian Federation in 1991, the former Academy of Medical Sciences of the USSR became the Academy of Medical Sciences of the Russian Federation, and continued to be

⁴ Raimo Miettinen Market potential of Northwest Russia for telemedicine applications

responsible for medical research. There are a number of clinics in Russia which belong to the system of the Russian Academy of Medical Sciences.

1.2.4 Regional level

The administrative units at this level govern regional healthcare. Prior to the 1993 legislation establishing a mandatory medical insurance system, regional governments had full control of regional funds for healthcare. Following implementation of mandatory medical insurance, they lost a portion of this control to the newly established territorial mandatory medical insurance funds (OMS Funds). Due to the only partial implementation of the health insurance system, however, regional and local governments currently retain a significant role in its management.

The regions must ensure compliance with federal programmes, in particular those focused on the control of conditions and infectious diseases defined as being of high social priority, but do not have to report to the Ministry of Health. Following decentralization in the early to mid-1990s, they enjoy considerable autonomy within their administrative units.

Regional healthcare facilities usually include a hospital of the general profile approximately with 1000 beds and a children hospital with about 400 beds with an out-patient department. There are also regional specialized healthcare facilities like infectious, tubercular, psychiatric etc. About a quarter of primary care facilities and over 70% of diagnostic centers are regional.

1.2.5 Local (municipal) level

In many larger cities rayon authorities appear to be actively engaged in the reform process, while in rural areas the health authorities' functions have tended to become the responsibility of central district hospital chiefs. Following the 2003 law On general principles of organization of local self-government in the Russian Federation, municipal level governments do not have to report to the federal or oblast level governments, though they do have to comply with Ministry orders. This poses a problem for health policy since rayons do not have to comply with oblast level health reforms or other policies, and are only obliged to provide statutory healthcare services within their jurisdiction. In practice, many regions and rayons have developed a negotiating procedure so that the local governments remain within the regional Ministry of Health sphere of influence.

Urban rayons (cities) typically have a multifunctional city hospital for adults with about 250 beds, and city hospital for children with about 200 beds. In addition, there are hospitals for emergency care, a 700-bed specialized hospital for infectious diseases and tuberculosis, maternity hospitals, mental and psychoneurological hospitals (of which a few are at the regional level), and other hospitals for invalids. Most primary care facilities, independent polyclinics, and some diagnostic centers are municipal.

In the case of rural rayons, institutions typically include a central hospital with approximately 250 beds, which may also serve as a polyclinic. Some rayons may have a smaller hospital with about 100 beds. There may be independent polyclinics (not part of a hospital), small polyclinics or "ambulatories" and health posts staffed by feldshers.⁵

⁵ S.Fokanov *Modern Russian Healthcare system*

Igor Akulin, Director of SOGAZ Insurance Group , Deputy Head of Medical Center SOGAZ:

The existence of a municipal level in the healthcare system is quite formal. In some rural areas or cities policlinics are called 'municipal', but I think it is not correct; formally they belong to the local (regional) authorities.

There are over 364 policlinics in St.Petersburg.⁶ However it is not correct to say that they belong to the municipal level in the city. The policlinics are financed through the district administrations (but not the municipalities, which is a separate level in Russia) and thus belong to the regional level of the Health Committee.

1.3 Financing system

The support of medical aid is financed by the OMS funds according to the basic program of mandatory medical insurance, and also budget funds of all-levels budget system of the Russian Federation in compliance with the Program of state guarantees of providing free medical aid to the citizens of the Russian Federation.

Appendix N2 Financing of Healthcare services in Russia (based on the Healthcare Development Concept of the Russian Federation until 2020) illustrates the main financial flows in the Russian healthcare.

According to the federal legislation the financial support of the activities of federal healthcare institutions is an expense obligation of The Russian Federation.

The financial support of the activities of healthcare institutions, placed under the authority of the Russian Federation subjects, is an expenses obligation of the subjects of the Russian Federation. If we look at the St. Petersburg budget the expenditures of the Healthcare Committee in 2010 constitute 41 626 million RUR and the revenues are 14 409 million RUR.⁷

The financial support of the activities of municipal healthcare institutions is an expenses obligation of the subjects of the municipality.

Financial support of the special medical aid providing activities in skin-venereologic, anti-tubercular, drug abuse, oncological clinics and other specialized medical institutions according to the Constitution is an expense obligation of the Russian Federation.

Financial support of the accomplishing governmental task of providing hi-tech medical aid to the citizens of The Russian Federation in medical institutions is an expenses obligation of the Russian Federation.

Alexander Mironenko, Head of St. Petersburg Regional Branch of All Russian Medical Association, Deputy Director of the St. Petersburg Institute of Ear, Throat, Nose and Speech, Honored Doctor of the Russian Federation:

The hi-tech medical services should be more accessible as there are still the lines. Before the crisis the government increased the financing of such medical services every year. If in 2000 the government could pay for 500 expensive operations on articulates substitutions, this year it is 5000. Everything incl. diagnostics is provided free of charge.

Our institute has a state order of 500 operations, each costs appr. 1 million RUR

⁶ TopPlan database

Funds allocated at the federal level from the federal budget go mainly to the Ministry of Health and Social Development, which in turn are to be used to finance training, research and public health activities, large investments and high cost treatments. Funds from the local budgets go to the local health authorities to finance the same activities as the federal government but at the local level. In addition, local budget funds are to finance contributions for the non-working and non-paying portions of their respective populations. These payments are to be made on a per capita basis agreed at the regional level, and cannot be below the average contribution made by employers for each worker.

1.3.1 Mandatory Medical Insurance (OMS)

In June 1991 the law On Medical Insurance of the Citizens of the Russian Federation was adopted. The changes concerning healthcare financing were as follows:

- the enterprises transfer insurance premiums for mandatory medical insurance of active population; the premiums have tax character;
- insurance premiums for mandatory medical insurance of non-active population are paid by the state control bodies at the expense of budgetary resources;
- the volume and conditions of free medical assistance within the framework of OMS are defined in the base OMS program confirmed by the government, and in regional OMS programs adopted by regional authorities and corresponding to the base program; the volume of insurance premiums are established in accordance with the adopted OMS programs;
- besides mandatory insurance, voluntary medical insurance (DMS) at the expense of resources belonging to enterprises and private resources of the population can also take place.

The insurance health model stipulated radical innovations. New entities - private insurance medical agencies appeared within the framework of the healthcare system. The enterprises and state control bodies which act as insurers must sign contracts with insurance agencies which, in their turn, select medical institutions and pay for preventive and general treatment rendered to the insured persons. The new model stipulated that new financial institutions should appear within the framework of the branch. These institutions accumulate budgetary and non-budgetary resources and have a legal right to effect transactions involving these resources.

Since the second half of 1993 the enterprises and institutions were obliged to transfer insurance premiums for medical insurance of their workers equal 3.6% of their payroll funds. Since 2009 it is 3.1%. These resources started to be accumulated on the accounts of regional and federal OMS Funds. However according to the prime-minister Vladimir Putin the Government plans to increase the insurance premiums from 3,1% to 5.1%. This will provide extra 460 billion RUB to the OMS budget. The government is also planning to give all citizens a possibility to choose insurance company themselves not via an employer.

The Table N2 Financing of Healthcare services in Russia (based on the Healthcare Development Concept of the Russian Federation until 2020) illustrates the main bodies involved and their relationships. A key feature of the new financing system is the establishment of a federal mandatory medical insurance fund (Federal OMS Fund) and territorial OMS Funds (one in each subject of the Federation) at the regional level.

⁷ The Budget of St.Petersburg for 2010, www.gov.spb.ru

The purpose of the territorial funds is to collect and manage insurance revenues from a 3,1% payroll tax of employers on behalf of the working population, as well as regional government contributions on behalf of the non-working population (children, pensioners, the unemployed, etc.), and distribute these funds to private, profit-seeking insurance companies or territorial OMS branches which then contract for care on behalf of their members. These institutions are to contract with providers and are to be funded by the territorial OMS Funds under contract on a capitation basis. The legislation allows insurers to act as care managers or providers by using salaried personnel in their own facilities, or by buying services from other care providers. Thus the law in effect allows for the development of health maintenance organizations and preferred provider organizations, although these possibilities are not explicitly mentioned in the legislation

It will be recalled that according to the 1993 legislation, insurance companies were to receive from the territorial OMS Fund a prospective per capita amount for each individual covered. They would then face the incentive to minimize their payments to provider institutions (through a selection of efficiency-enhancing, prospective payment methods), and thereby maximize their profits. However, eventually, territorial OMS Funds began reimbursing insurance companies (and/or fund branches) retrospectively. This arrangement completely eliminated any incentive the insurance companies may have had to engage in selective contracting and pursue efficiency and quality-enhancing measures for providers. If the expenditures of the insurance companies are greater than the allowable amount, the territorial funds cover the deficit. The insurance companies' profits are a fixed percentage of each intervention billed to the territorial fund.

With an assured income, the insurers have no incentive whatever to impose cost-saving behavior on the providers. Moreover, they also have an incentive to collude or make agreements with the providers to increase the volume of services in order to increase their profits. As long as the insurance companies do not behave as real risk-bearing institutions, without assured profits, the potential benefits of increased provider efficiency will be lost.

This discussion has focused on insurance companies, however it is equally valid for the case of the territorial OMS branches, which, since they are part of the mandatory health insurance system, will clearly have no incentives to behave as risk-bearing institutions.

According to the legislation the consumer is free to choose the insurer, thus in effect also choosing the insurer's contracted provider. This freedom of choice is important not only as a key to increased consumer satisfaction, but also as a spur to insurer and provider competition. In practice, however, consumer freedom of choice is constrained by the limited availability of insurers in many of the regions. Even where there are many insurers, division of the population into "sectors" or "spheres of influence" of insurance companies in effect precludes consumer choice. In these situations, freedom of choice in effect means little more than freedom to choose a physician within a polyclinic. Under an incentive system which rewarded doctors for the quality of services rendered or for their workload, even this choice should have some positive impact on service quality. However, as doctors continue to be paid by salary for the most part, their only reward for being preferred by patients is an increased workload with no corresponding financial remuneration. Therefore any potential benefits of increased competition due to free consumer choice are lost.

Implementation of the health insurance law has met with numerous obstacles. The law has in fact been only partially implemented, and there are very broad interregional variations in the financing patterns that have emerged. The competitive, market-based model has failed to emerge except in isolated instances, and the expected increase in

financial resources and improvements in efficiency was not as great as had been hoped. There are ongoing discussions about the future role of the insurance carriers. There is a growing tendency to view them as wasteful bureaucratic agencies that rather impede efficiency in the new financing mechanism, and some regions have gone so far as to have got rid of them altogether.⁸

Ultimately, the objective of the new insurance system to increase overall funding for health care has not been met, as the system continues to be severely under funded.

1.3.2 How Healthcare Facilities are Financed?

Historically hospitals were paid through 'line item' budgets, based largely on bed numbers. Polyclinics received funds according to a similar formula that used a notional number of visits in lieu of beds. These budgets were increased each year on the basis of a centrally agreed figure that covered inflation, growth, etc. There were, therefore, perverse incentives to expand facilities in order to command greater resources. The shift to a financing system based in part on insurance mechanisms was intended to address these issues and, through insurance-based pricing pressures to create incentives for hospitals to reduce the length of stay and to use diagnostic tests and investigations more rationally. The prospective payment method was to fix the price for any particular inpatient case against a schedule of diagnostic classifications. Payments to polyclinics were to be by a variety of methods, providing encouragement to treat patients in the ambulatory setting rather than referring them on to hospitals. In addition, it was expected that hospitals and polyclinics would receive some 30% of their finances from the region based on their actual costs. In practice the operation of the new funding has been more complex and the payment of hospitals has varied from the original proposals.

If we have a look at the Appendix 2 we can see that at present a regional healthcare institution (a hospital for example) has 4 sources of financing:

- from the territory OMS Fund or insurance organizations for staff salaries, incl. social security payments, drugs, clothes, meals for patients etc according to the Tariff Agreement. (OBS! Receives after a service was provided)
- from the regional authorities for a number of services according to the state order, hi-tech services, investment (equipment etc), facility management (maintenance of healthcare facilities)
- from insurance companies according to the tariffs of voluntary medical insurance programme (DMS) (OBS! Receives after a service was provided)
- from patients for paid services according to the tariffs of the hospital.

A hospital can also receive extra financing from OMS Fund, regional authorities, members of the Legislative Assemblies within specific programmes.

Igor Akulin, Director of SOGAZ Insurance Group, Deputy Head of Medical Center SOGAZ:

The system is very centralized. The management of the public hospital has a right to decide about the closing of some departments (but not the main ones which are controlled by the Healthcare committee), make staff changes, carry out everyday management functions (incl. quality control). The hospital can also organize small public procurements, but for not expensive products and services.

⁸ S.Fokanov *Modern Russian Healthcare system*

The Tariff Agreement which is the same for all regional healthcare facilities is set up by the regional Tariff Commission which in St. Petersburg consists of representatives of St. Petersburg Healthcare Committee, Territorial OMS Fund, insurance companies and healthcare community.

A two-channel financing system causes a number of problems in financial management of healthcare organizations. They become less motivated in optimization of facility and energy management.

The insurance companies or the territorial funds (or their branches) in their absence, pay providers retrospectively. Retrospective payments, however, completely eliminate any possibility of influencing hospital behavior with a view to creating cost savings. The problems arising from this method of payment therefore involve two separate though closely related issues: the questionable role of the insurance companies, and the impact on the behavior of hospital providers.

Igor Akulin, Director of SOGAZ Insurance Group, Deputy Head of Medical Center SOGAZ:

Insurance companies could suggest to close some hospitals but the authorities will never allow it. As a result a number of inefficient hospitals exist. The situation could be changed if the financial flows were transferred to better public hospitals thus increasing their quality.

1.4 Public procurement

In 2005 Russia adopted new legislation on public procurement within the context of administrative reform aimed at implementing transparent, effective and non-discriminatory procurement proceedings. By adopting the new law, the federal government set up a unified system of public procurement for all state and municipal contracting authorities, among which are state bodies, state extra budgetary funds, local authorities, budget-financed institutions and other recipients of federal, regional and local budget funds.

In general, Russian public procurement legislation is based on the provisions of the Civil Code and the Budgetary Code of the Russian Federation and consists of the Law On Placement of Orders for Procurement of Goods, Works and Services for State and Municipal Needs' (2005) and other specific laws, including the Federal Law on State Order for Defense (1995) the Federal Law On State Material Reserves (1994), the Federal Law On Supplies for Federal Government Needs (1994) etc, which govern procurement of specific types of goods. Over 30 regulations have been passed since the Public Procurement Law was adopted.⁹

Supervision over public procurement, except for control over the state order for defense, is exercised at the federal level by the Federal Antimonopoly Service of the Russian Federation (FAS), and at the level of the constituent entities of the Russian Federation or the local municipal bodies by the respective authorized supervisory body.

The data on public procurement and tenders is now published in the Internet. The federal site **www.zakupki.gov.ru** informs on federal procurements and contains a list of the regional sites which are in charge of publishing the data on regional procurements.

As the reforms are ongoing, there are still various different systems of public procurement. The Ministry of Healthcare and Social Development or the Federal

⁹ Falk Tischendorf, Kamil Karibov and Ekaterina Soboleva. Public procurement 2009: Russia (Beiten Burkhardt)

Mandatory Medical Insurance Fund organizes the tenders on the federal level; on a regional level the Healthcare committee of the Regional Administration or a special department for public procurement or the territorial mandatory medical insurance fund fulfill the task; on the municipal level - the relevant municipal authorities are responsible. All these official bodies organize the tenders based on the inquiries of the medical institutions. Furthermore, the medical institutions can announce tenders independently if the sum to be spent is within limits.

The Public Procurement Law differentiates between placing an order by way of holding a sale (in the form of a tender or an auction) and placing an order without holding a sale in cases explicitly stipulated by law (by call for bids or with a single supplier or at commodity exchanges). At present, auctions are regarded as the most effective and transparent form of public procurement. Around 70% of all public procurement procedures are conducted in the form of an auction.¹⁰

In a tender procedure, the contract will be awarded to the bidder that has offered the best terms and conditions for implementation of the pertinent contract, including, but not limited to, the contract price. Each criterion shall be listed in tender documentation and its weighting shall be determined.

As for an auction, the winner of an auction is the bidder that has offered the lowest contract price. The bidder that has filled a bid complying with all the requirements established in the notice making the call for bids and that provides the lowest contract price is declared the winner. When several bidders present a similar lowest price, priority shall be given to the bidder whose bid is received before that of other bidders.

The Public Procurement Law provides for a number of exceptions, when an order can be placed with a single supplier without carrying out a competitive procurement procedure. The following cases related to this matter are of particular interest:

- supply of goods, execution of works, and provision of services that fall within the sphere of activities of natural monopolies;
- services in the spheres of water supply engineering, water disposal, sewage, heating, gas supply (except for services related to the sale of liquid gas) are rendered in accordance with prices specified in the legislation of the Russian Federation;
- a production or service necessity arises, which execution or rendering can be fulfilled exclusively by an executive body according to their powers or by their subordinate state institutions, state companies the respective powers of which are determined by regulatory legal acts of the Russian Federation, and by the legal regulatory acts of the constituent entity of the Russian Federation. In such a case, a customer is obliged to inform the FAS (if procurement is carried out for federal needs) or other supervision authority (if procurement is carried out for the needs of a constituent entity of the Russian Federation or a municipal entity) not later than within one working day of signing the contract;
- orders for the supply of goods, execution of works, rendering of services for state needs are placed with a supplier (executor, contractor) who has been assigned by an order or regulation of the President of the Russian Federation.

¹⁰ Falk Tischendorf, Kamil Karibov and Ekaterina Soboleva. Public procurement 2009: Russia (Beiten Burkhardt)

According to unofficial figures, the number of state and municipal orders placed with a single supplier has quadrupled during the past three years.¹¹

The Public Procurement Law prohibits conducting negotiations with a bidder during the placement of orders through tender or auction. However, if an order is placed with a single supplier, the negotiated procedure can be conducted according to the rules set forth by the Civil Code for the conclusion of contracts for the supply of goods or rendering services for state or municipal needs.

The contract is usually signed for 1 year. The Public Procurement Law does not contain any regulations regarding the procedure for extending an existing contract. However, relevant court practice indicates that a contract prolonged by an additional agreement, without holding a tender, will be void.¹²

The success of the participation in a tender highly depends on the knowledge of the system. The volume of documents which should be presented in a rather short period of time to the state organizations in Russian is very big. Also, it should be noted that it is impossible to protect commercial information which has to be presented during the tender.

Alexander Golyshev, Chief Doctor of the Children's Clinical Hospital №5 named after N.F. Filatov:

The hospital is allowed to organize tenders up to 5 million RUR. If the value of the contract is higher the tender is organized by the Healthcare Committee or Committee for Investments (if it is a strategic project).

My recommendation for the Swedish companies is to take an active part in the development of requirements specifications in cooperation with the healthcare provider.

Alexander Mironenko, Head of St. Petersburg Regional Branch of All Russian Medical Association, Deputy Director of the St. Petersburg Institute of Ear, Throat, Nose and Speech, Honored Doctor of the Russian Federation:

There are almost no limits on promotion of equipment, instruments etc. A contract is usually signed with the healthcare organization which provides an opportunity of making a presentation for the doctors of the institution during a special meeting or a regular weekly meeting.

The decision is taken by a commission of a minimum of five persons who should have no personal interest in the outcome of the tender. Typically, the commission includes representatives of the Federal or Regional Healthcare Ministry/Committee, the Ministry/Committee for Economic Development and Trade, the Mandatory Medical Insurance Fund and the special Public Procurement Department. Most of the time government officials are more concerned about the price rather than the quality. The influence of the academics, professors and their attitude towards the products is rather high. It is also of great help to have reliable partners in Russia who know all these factors. A good network of contacts is of highly importance.

¹¹ Ibid

¹² Falk Tischendorf, Kamil Karibov and Ekaterina Soboleva. Public procurement 2009: Russia (Beiten Burkhardt)

PART 2 PRIVATE HEALTHCARE SYSTEM

2.1 General Overview

Private medical aid – is rendering medical service by medical workers outside of state and municipal institutes of healthcare system, using private finances of citizens or enterprises, institutes or organizations, including medical insurance organizations, according to the made agreements.

Private medical practice is realized in compliance with the Constitution, other federal laws and regulatory acts of the Russian Federation, laws and other regulatory acts of the subjects of the Russian Federation and has equal rights with the public healthcare system.

The right to provide private medical aid has an individual, who has got a diploma of higher or average medical education, certificate of specialist and license for medical activities.

In the beginning of 1990s a system of voluntary medical insurance and private clinics came as an alternative to public facilities and shadow healthcare sector.

The system of paid medical services started to form in Moscow from the end of 1980s when medical cooperatives were established. The Moscow citizens' life level and ability to pay is traditionally higher than average indicator in Russia. The part of population that has high and middle level of incomes in Moscow – the main customers in the sphere of private healthcare - is quite high. At the same time imperfection of insurance medicine, absence of clear medical norms for counting salaries of medical staff in municipal institutions led to the outflow of skilled personnel to the institutions, providing paid medical services.

Alexander Golyshev, Chief Doctor of the Children's Clinical Hospital №5 named after N.F. Filatov:

In the middle of 1990s when the OMS system was introduced and the state support of the public healthcare facilities was very low, legalization of paid services became the only way out from the difficult financial situation. It gave us a chance to keep qualified personal in the public sector and follow the new technologies.

Moscow took the leading position in the number, quality and variation of paid medical services provided. One of the most attractive factors for the development of the paid medical services market in Moscow was a scientific base of the Health Ministry and the Russian medical science academy, Governmental apparatus, medical universities and other institutional systems. Before the Perestroika it was hardly possible for an average citizen to get a medical referral for treatment to elite hospitals and especially to get consultation from high trained specialists and on the modern equipment.

In 1996 the Russian Government determined the order of providing paid medical service on the basis of licensing of public and private healthcare institutions.

According to the opinions of Moscow healthcare committee's specialists in 1997 over 4 million people were at least once provided with paid medical services. At the same time there could be counted not more than 10 million people that had used legal commercial medical services in the country.

Dental care services became first provided by private healthcare system. There were about 2000 out of 3000 clinics in Moscow that specialized in dental care, all the rest were multifunctional centers.

First multifunctional private clinics were established in Moscow and St. Petersburg. In other regions they started to appear only in 1999. Until that time there were only paid services at the public healthcare institutions and dental clinics. The first branches of western medical clinics were established in Russia also only in 1999.

Private provision, while legally permissible, has yet to develop to a significant extent in the health sector, though there is evidence of emerging private activity with a potential for growth. The health sector was not incorporated in the plans for rapid privatization that overwhelmed other sectors; it was intentionally excluded on the grounds that health care facilities and providers should not become profit-seeking institutions, so as to uphold the principles of equality and access to services.

Although private practice is permitted, it is not supported by the state. Constraints to the development of a private sector in healthcare include very high taxes and capital requirements for the purchase of medical facilities. This gives rise to very high prices for privately provided services.

Private health care institutions have been operating without a well developed legislative basis; moreover they started to develop later than private businesses in other sectors. In health care private provision has developed fastest in case of dental care. Hospital care remains concentrated in the public sector. Private healthcare providers are striving for prohibiting of paid services in the public sector as due to the low rates (which take into consideration only staff costs and pharmacological supply, but not equipment, facility services etc) unfairly compete with the more expensive private services.

Marina Alekseeva, head of the department of quality control of the St. Petersburg Healthcare Committee (from Anastasia Karimova. *Clinical dependence*):

A number of complains on private healthcare providers grew by 30% in 2009 partly because of bad management and patients' overstated estimations. In 90% of these cases patients were not satisfied with the quality of private dental care.

In 2008 a Draft Concept on Private Healthcare System Development was introduced by the First Russian Association of private medical practitioners. As it was stated there a share of state and foreign investments in the Russian healthcare system is very small now. It is very important to develop public investments and loans system, incl. tax and rent preferences, medical equipment leasing support mechanism etc.

In 2006 an Association of Private Clinics was created in St. Petersburg with the main objective to contribute to equal rights of public and private healthcare facilities. The representatives of the Association are members of the working groups of the St. Petersburg Healthcare Committee, Russian State Duma, expert council on competition development in social and healthcare sectors of the Federal Antimonopoly Service of the Russian Federation (FAS).

The association unites 16 private healthcare organizations in St. Petersburg:

- AVA-Peter Clinic (networks of clinics, incl. Scandinavia Clinic)
- American Medical Center
- EuroMed Clinic
- EMC Clinic (Emergency Medical Consulting)
- CardioClinic
- Clinic named after N.I. Pirogov

- CORIS Assistance
- Medical Center “The XXI-st Century” (networks of clinics)
- Baltic Medical Clinic (network of clinics)
- Medical Unit № 157
- Network of Clinics “ONA”
- Maternity Hospital № 2
- The Center for Heart Medicine "Black River"
- The multifunctional clinic "Alliance Eurasia Medicine"
- MEDEM International Clinic & Hospital
- S.M. Berezin Medical Diagnostic and Treatment Center of the International Institute of Biological Systems (networks of clinics)

These are the largest private healthcare providers, excl. MEDI network of clinics and a new medical center of Sogaz insurance company to be opened in the center of St. Petersburg opposite the Consulate General of Sweden in June 2010.

There are appr. 1200 private healthcare providers in St. Petersburg, incl appr. 800 dental clinics of different size. Appr. 20% of private clinics are in the sphere of gynecology and urology and only 10% (i.e.10-12) are multifunctional centers.¹³ A lot of doctors in the private clinics work part time in the public sector.

Igor Akulin, Director of SOGAZ Insurance Group, Deputy Head of Medical Center SOGAZ:

There are multifunctional clinics in the city, but their total bed capacity doesn't exceed 200 beds. It is not serious. Private clinics don't stand competition with the public ones.

New clinics are opening in the city. The existing multifunctional clinics open branches in different city districts. For example during the last 2 years Scandinavia clinic managed to open 9 district branches.

A rapid growth of client database of private healthcare providers is determined by an opportunity of patient choice of a specialist as well as better medical services.

Igor Akulin, Director of SOGAZ Insurance Group, Deputy Head of Medical Center SOGAZ:

The demand on private healthcare services exists and increases, which is connected with the increasing dissatisfaction of population with the public healthcare system. As an insurer I am also not very happy about the service provided by the public institutions. It is easier for me to address a patient to a private clinic, where he will be ideally treated from the service point of view. We address a patient to the public hospitals only in very serious cases when the treatment can't be provided in a private clinic. Specialists in complex pathologies work only in public hospitals, but then we constantly need to control the level of service provided for such patients.

¹³ Private medical business in St. Petersburg has passed a phase of establishing but lives in a phase of survival, www.coris-spb.ru

AVA-Peter clinic has started the first public-private project (PPP) in Russia in Kazan. It is a construction of the perinatal center with 51% of private investments (appr. 13,4 billion USD). The rest is owned by the government of the City of Kazan which provided a lot and a building. According to some specialists the success of the project was determined by a big interest of the city authorities in the implementation of such a socially significant project.¹⁴

2.2 Private Healthcare Providers and OMS system

According to the federal and regional legislation healthcare organizations can participate in the OMS system regardless to the form of ownership. In 2008 there were 183 out of 30 000 private healthcare providers in Russia that have obtained a right to participate in the OMS system and receive money from the territorial OMS Funds for providing services to the public via arbitral court. In St. Petersburg it is hard to provide an exact number of such clinics: according to specialists there are from 4 to 31 clinics (out of appr.1200)¹⁵. However it is well known about the success experience of 5: Cardio clinic, Scandinavia, Capital express, ONA and ONA-MRT center.

The main argument of those who are against including private clinics in the OMS system is that the OMS tariffs are much lower than the tariffs of the private sector and a patient will need to pay difference out of pocket, which is unfair as according to the Constitution everyone has a right to free medical aid.

Introduction of new tariffs and a single-channel financing model which is expected in 2010-2011 is a very important step for private actors. At present OMS tariffs cover only appr. 50% of the private costs (as public have also other financing channels). However introduction of single-channel financing is not a complete solution as another obstacle for private specialized clinics to participate in the OMS system exists. A patient needs a referral to a private specialist/clinic from his GP, working in a public policlinic, which is almost impossible to obtain as the GP will need than to justify why this service can be provided in the same volume and on the same level only in the private institution¹⁶.

Jakov Nakatis, chief doctor of L.G. Sokolova Clinical Hospital № 122 of the Federal Medical-Biological Agency of Russia:

If the law is followed and private healthcare providers receive a right to participate in the OMS system, the healthcare system will only win as the participation of commercial organisations in healthcare programmes will contribute to fair competition which will lead to the quality development of medical services.

On the other hand the tariffs for hi-technology services in the public sector are very competitive with the private sector. For example every year the government of the Russian Federation and the City of St. Petersburg make a state order of angioplasty¹⁷. The tariffs for such a service are 120 000 RUR and 214 000 RUR in St. Petersburg resp. Russian Federation. As it was stated by Nadezhda Alexeeva, Director of St. Petersburg Cardio Clinic the price of such operation in their private center is 124 000 and they are very motivated to compete with the public sector. As they were explained by Roszdravnadzor it is needed to obtain an extra license on providing hi-technology services besides other licenses they have for provision this treatment on a private basis.

¹⁴ Elena Denisenko. *Looking for the cross-points (2008)*

¹⁵ ibid

¹⁶ Anastasia Karimova. *Clinical dependence (2010)*

¹⁷ Angioplasty is the technique of mechanically widening a narrowed or obstructed blood vessel; typically as a result of atherosclerosis (Wikipedia).

Nadezhda Alexeeva, Director of St. Petersburg Cardio Clinic:

In order to get this licence a list recommendations on 12 pages should be followed incl. availability of very expensive equipment of general character which is not needed for a specialised clinic and can be offered only in very big multifunctional state hospitals.

4 main steps for the development of private healthcare in Russia are needed on the current stage:

- development of legislation on private healthcare;
- facilitation of self-regulation in healthcare (see Conclusions);
- development of better conditions for investments attraction and preferential crediting of healthcare organizations
- development of PPP

2.3 Voluntary Medical Insurance (DMS)

Voluntary medical insurance (DMS) was first authorized in Russia in 1991, with further regulatory legislation the following years. DMS is provided to individuals or groups, for example the staff of an enterprise, and allows the population covered to obtain additional services beyond those included in the basic package. It is offered exclusively by private insurance companies which operate for profit.

According to the Federal law on mandatory medical insurance legislation (1993), DMS may be offered by private insurers who are part of the mandatory medical insurance system (OMS).

In general, it tends to be purchased mostly by employers for their staff. The legal person purchases policies for its employees that give the right for getting medical aid in established public or private institution in the volume that is foreseen in the insurance contract. Private insurance firms have tended to concentrate on the top end of the market and to offer add-on services to supplement the basic package of free medical care. Their focus has been on providing better conditions, offering 'patient choice' of a doctor and on securing access to more prestigious institutions. Companies tended at the beginning to draw up contracts with the clinics and hospitals that previously formed part of the closed system, which were better resourced even in the Soviet era. They were thus able to guarantee their clients access to better facilities and to higher caliber staff. Later on the companies started active including of newly opened private clinics in the insurance packages. Some insurance companies like Capital-Polis and Sogaz opened their own multifunctional clinics to control the quality of medical services and avoid extra high invoices from healthcare providers.

The cost of DMS programs varies depending on the spectrum of services that are included. The basic programs include all the medical and diagnostic aid from GP and specialists, an opportunity to call a doctor home and make an expertise of temporary disability (handing out sick leave certificates). These programs can also include dental care, emergency medical aid and CPR, hospital treatment, surgical and conservative treatment, physiotherapy, massage in some cases, costs of medical drugs and other necessary medical means.

There are some special programmes with a focus on specialized care, like dental care, pediatrics or emergency medical aid etc.

The average price of medical services by specialization in Russia, 2009 (in RUB per service)¹⁸

Allergology	446,5	Otorhinolaryngology	529,1
Gastroenterology	478,9	Ophthalmology	477,5
Obstetrics and Gynecology	528,2	Pediatrics	508,1
Venereology and Dermatology	932,1	Preventive dentistry	547,5
Other specialties	512,2	Traumatology and Orthopedics	433,6
Cardiology	770,6	Urology	506,0
Cosmetology	486,6	Physiotherapy	456,5
Mammology	491,4	Dental surgery	552,6
Manual therapy and massage	394,5	Surgery	376,3
Neurology	693,3	Endocrinology	637,2
General medicine	432,7		

Cosmetology is not dominated by the number or total value of services provided, but it has the highest average prices, as well as in surgery and manual therapy.

Irina Mayorova, Board Member of the Regional Association of Healthcare Managers:

The prices for paid services in the public healthcare organizations are lower than in the private ones. The public clinics are also trying to reach the same quality standards as in the private clinics, but in the most cases a patient in Russia goes to a specialist he knows, and it is less important for him if the doctor works in a public or private clinic.

The analog is assignment of a patient to a multifunctional clinic, which is supposed to guarantee a complex of prepaid medical services. In this case a patient communicates with the medical institution direct without an insurance company. The programs offered by medical institutions are as various as in the sector of DMS. The price is almost the same.

DMS for the client is not tied to fixed prices of medical services, as it is purchased for a long period of time for the stated price. But the number of the services that can be provided is determined.

¹⁸ Analysis of the healthcare market in Russia and forecast 2011-2014. (BusinesStat, 2010)

Nadezhda Alexeeva, Director of St. Petersburg Cardio Clinic:

DMS clients can be up to 50% of the total patient flow in multifunctional clinics of the middle price category. They are more like upgraded policlinics with a wide range of specialists available in the same building. Specialised clinics like ours are not popular among insurance companies for DMS (only 10-15% of the total patient flow) as it is offered only as an exclusive service for VIP clients.

Also the clinics that provide services according to such agreements receive reimbursement for all the patients they take. The insurance organization keeps the difference between the insurance fee and the payments to the medical institutions.

In DMS turnover natural persons' insurance policies take not more than 15%, and this proportion is expected to be kept during the next years. The corporate insurance segment is close to saturation in Moscow, and now it is expected to be growing in other regions including St. Petersburg.¹⁹

Socio-demographic groups of patients are not equally represented in the private healthcare system. Women, people of working age, and urban residents consume private medical services more than others.

Forecast of the structure of private patients according to age, years 2010-2014 (in millions)²⁰

	2010	2011	2012	2013	2014
Younger than working age	11,0	11,1	11,4	11,9	12,3
Employable	48,7	48,8	49,0	49,5	49,8
Pensioners	8,9	8,9	9,2	9,4	9,6
Total	68,6	68,8	69,6	70,8	71,7

Working-age population consumes the most part of paid medical services in Russia. According to the standards of Federal Statistics Service, working age is defined as 16-64 for men and 16-59 for women. The reasons are higher incomes, corporate voluntary medical insurance (DMS), gender activity, including birth of children.

Alexey Kuznetsov, general director of Capital-Polis insurance company (from Anastasia Karimova. *Clinical dependence*):

DMS charges in 2009 in St. Petersburg decreased by 15% and insurance payments increased by 10-15%. In 2008 DMS was offered to the employees of 65% of companies participated in Ancor recruitment holding, while in spring 2009 only by 58%. In autumn 2009 a lot of companies introduced insurance package back, but they became much cheaper and not that extensive.

In There are plans to revise the laws on voluntary medical insurance, with a view to improving the regulation of the system, extending coverage and encouraging take-up. The 1997 "Concept of health care and medical science development in the Russian Federation" and Healthcare development strategy until 2020 assert the need to develop voluntary insurance, but there have been no further initiatives yet.

¹⁹ Analysis of the healthcare market in Russia and forecast 2011-2014. (BusinesStat, 2010)

²⁰ *ibid*

Igor Akulin, Director of SOGAZ Insurance Group, Deputy Head of Medical Center SOGAZ:

The DMS market in St. Petersburg is appr. 3 billion RUR and appr. 300-400 insured. As you may see one insurance costs 10 000-15 000 RUR per person. So the market exists and it is developing.

Development of voluntary medical insurance should be closely connected with differentiation of paid and free medical services in public healthcare organizations. Another priority is a development a system of co-financing of healthcare services at private healthcare organizations together with OMS system.

2.4 Certification, registration and licensing procedures

2.4.1 Medical equipment, instruments and materials

As in most countries, in Russia a medical product can be admitted to the domestic market only when and if it has been found in conformity with technical and medical safety regulations pertaining to this particular product. According to Evgeniy Mirononenko, director general of “The Center of the medical and technical tests by R.R. Vreden” Company Limited, which assists in certification of medical equipment, “registration procedure is the entrance document the Russian market”. The procedure of registration is the same for all medical equipment, instruments and materials be it X-ray equipment or bandage.

While entering the Russian market with any medical equipment, instrument and materials you have to follow two main procedures:

- Step 1: registration;
- Step 2: certification.

Before receiving a certificate of conformity, a company should register its product at the Ministry of Healthcare and Social Development. According to the Order № 23, dated January 23, 1996, issued by the Russian Ministry of Health, it is prohibited to purchase and use foreign-made medical equipment in Russia without it being registered by the Ministry of Health. Upon registration, all imported medical equipment and devices are added to the National Register of medical equipment allowed for use in medical treatment in the Russian Federation.

Assessment of conformity of medical equipment and products to existing safety standards is carried out now by the Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor). The Service has a Russian-language web site containing a section devoted to registration of foreign medical equipment and other medical items at <http://www.roszdravnadzor.ru/registration/zarub>

The site also publishes contact information for the staff of the Department of Registration of Foreign Medical Equipment and Devices who are directly involved in registration of foreign-made medical equipment. Experts of the Department do not provide consultation by phone and prefer meeting in person with authorized company representatives to discuss registration procedures and documents and solve problems whenever necessary. The business language of these meetings is Russian. Registration is given on the basis of a set of tests and estimations, which confirms the quality, efficiency, and safety of the product. Time of validity of the registration certificate is not limited now.

Procedure of registration begins with collection of original documents, which are supplied by the manufacturer of a medical product. These documents are:

- Cover Letter (Does not require any certifying).
- The Power of Attorney to Russian Company responsible for registration. (With notary certification and apostille).
- Evidence of manufacturer's official registration, i.e. Certificate of Incorporation, Establishment Registration Database etc. (Duly certified by local Chamber of Commerce and apostilled).
- Certificate of quality management system. (With notary certification and apostille).

In other words, these documents should confirm the fact that the product was registered in the country of origin as medical device as well as prove the quality of manufacturing process. Examples of such documents include:

- ISO 9001, ISO 9002, ISO 13485, ISO 13488 certificates which should be notarized in the country of origin and have an Apostil,
- Certificates of registration of medical equipment issued by a respective government agency in the country of origin such as FDA certificates, EC Certificates (CE Mark) and Declaration of Conformity. All these certificates should be notarized in the country of origin and have an Apostil,
- Certificate of free sales,
- Electrical safety and EMC (electromagnetic compatibility) certificates.
- E Certificate, Free Sales Certificate or smth. of the kind. (With notary certification and apostille).
- Declaration of conformity (With notary certification and apostille).
- Leaflets (min. 3 sets).
- Information about medical product or medical device to be registered (Test Reports, Technical File, Used Materials List. etc.).
- Instructions/manuals.

Please, see Appendix 3 with a full list of required documents.

In order to undergo tests, a sample of the equipment or device must be imported to Russia. To be able to bring the sample product into the country the manufacturer or its authorized representative should apply to the Ministry of Health and get the appropriate permission to show at the customs point. The same rules are applied when equipment is brought to the country for showcasing at an industrial exhibition.

All interaction with the Russian authorities is handled on behalf of the exporter/ manufacturer of medical products by a duly authorized Russian representative.

There are four stages of registration procedure:

1. The authorized company representative has to meet with an expert from the Department of Registration of Foreign Medical Equipment and Devices and submit documents necessary for registration. The Department will review documents, make a decision on accepting the documents for registration.
2. The Department will further do in-depth examination of documents and decide the types (usually technical, clinical and toxicological and/or others) and the scope of

tests that the medical equipment should undergo, if necessary. The variety of possible tests includes:

- electrical safety;
- electromagnetically compatibility;
- radiation safety;
- safety of electromagnetically and light emanations;
- toxicological tests;
- clinical studies

3. The samples will be sent for testing to special centers and laboratories. In some cases, companies will execute testing of samples prior to submitting the documents.

4. The results of the tests will be sent to the Department of Registration of Medical Equipment and Devices for final review, approval and issuing the registration certificate.

As it was mentioned above the time of validity of the registration certificate is not limited. But the Russian Health Ministry will renew or amend the registration license if:

- License has expired;
- Manufacturer's name has changed;
- Another manufacturer is producing it;
- Product's name has changed;
- Product has been upgraded or modernized;
- Application area or usage directions have changed;
- Producer has changed specifications or regulations;
- Changes do not conform to Russian or international standards;
- New materials in the product contact with human body.

Manufacturer/exporter must inform Russian Federal Authorities of any contingencies that may require amendments in the registration papers.

If you want to escape any problems during registration procedure you have to follow the rules, be result-oriented and conform. If you apply for registration through accredited Russian company you reduce the possible risks and troubles. The registration procedure can be issued only by the Russian company.

Time of getting registration certificate is approximately 3 month but in a good scenario if there are no any difficulties on every stage.

Price depends on the product and tests, the overall cost may range from a few thousand to several tens of thousand USD. The cost comprises:

- Consulting fee
- Translation and authentication of translation;
- Health Ministry Experts fee
- Tests and clinical studies
- State Registration fee

Once the Federal Registration has been obtained, you will need to apply for a GOST-R Certificate of Conformity and a Sanitary (Hygienic) Certificate. These two certifications

can only be issued after the registration certificate is obtained. Usually both certificates are issued in the name of the distributor who bears the costs.

Mandatory certificate of conformity GOST R - is approval of compliance of production to the requirements of technical regulations (safety requirements).

Evgeniy Mironenko, , General Director of The Center of the medical and technical tests by R.R. Vreden (Medical Equipment Certification):

There is a list of foreign equipment which requires obligatory certification:

- *Dental material*
- *Medical supplies*
- *Medical electric devices*
- *Low-frequency devices for electric treatment*
- *High-frequency and quantum devices for electric treatment*
- *Implants*
- *Medical equipment*

GOST R certificate is issued for a term of one year (for a shipment or several shipments under one contract) or three years (if experts of Gosstandart visit and assess a foreign producer's manufacturing facility in the country of origin). Production, specified in the certificate, can be supplied to Russia during certificate valid time according to contracts to different companies registered in Russia.

Terms and prices of issuance of Mandatory certificate of conformity GOST R depend on production specificity, availability of other certificates, technical documentation for products, as well as on peculiarities of laboratory testing. On submittal of all documents period of issuance of Mandatory certificate of conformity GOST R for 3 years ranges from 2 to 20 days.

Sanitary and epidemiologic conclusion (hygienic certificate or SEZ) is issued by Federal service on supervision in the field of protection of consumer rights and public well-being (Rosпотребнадзор). Hygienic certificate confirms the conformity of product's properties to the state sanitary and epidemiologic rules and regulations.

Sanitary expertise precedes the mandatory GOST R certification. Hygienic certificate number and the date of its issue have to be included in the GOST R certificate.

Term of validity of the hygienic certificate depends on the kind of product covered and may vary from 1 month to 5 years.

Cultural and language barriers continue to be a significant challenge to foreign companies attempting to register medical equipment by themselves without appropriate legal advice or help from experienced distributors or consultants.

2.4.2 Pharmaceutical products and services

Procurement of registration certificate for drugs and pharmaceutical substances has another procedure. It is also provided by the Federal Service for Supervision in the Sphere of Healthcare and Social Development (Roszdravnadzor).

The Ministry of Healthcare and Social Development of the Russian Federation developed and approved "Drug agents state registration regulations", "Provision on compact drug agents registration procedure", OCT № 91500.05.001.00 "Quality

standards for drug agents. fundamentals". The state registration includes assessment, pre-clinical and clinical researches, approval of the normative documentation for drug agents.

Clinical testing is an important stage of drug agents registration procedure. The Roszdravnadzor arranges carrying out of clinical researches together with FGU "Research center of medical products", Pharmacological Committee, MIBP Committee and Committee on ethics by the federal body controlling quality, efficiency, safety of drug. In accordance with the federal law On Drug Agents, drug agents developers and sponsoring companies are granted with the right to choose clinical bases.

According to the Article 11 of the Drug Agents State Registration Regulations after the registration Roszdravnadzor issues the registration certificate for drug agent to the declarant. Thereto according to the section 02.03.01 of the State Information Drug Agent Standard registration certificate, legal document confirming the fact of official authorization of drug agent circulation (in the form of medicine). In the mentioned section there is a full list of data which must be contained in the registration certificate. Please, see Appendix 4. List of documents, necessary for registration of foreign drug agents

Registration procedure is complicated and expensive.

Times and value of issuance of the Registration certificate for drug agents and pharmaceutical substances depend on many factors, availability of certificates, full documentation list, and peculiarities of assessment, results of pre-clinical, technical clinical, pharmacological, toxicological and medical tests. Upon tendering all documents period of issuance of the Registration certificate varies from 6 to 9 months.

Pharmaceutical activity also requires licensing.

Regulations on Licensing of Pharmaceutical Activity approved by the Decree of the Russian Government on 1 July 2002 № 489 stipulates the licensing of pharmaceutical activities of legal entities. According to the law the pharmaceutical organizations caring out activities in wholesale trade of medicines and pharmaceutical institutions including retail and wholesale trade of medicines, as well as the manufacture of medicines must obtain Pharmaceutical Licensing. It is issued by the Ministry of Healthcare or the executive authorities of territorial entities of Russian Federation, which the Ministry has been transferred by agreement with their licensing authority for these activities (hereinafter - the licensing authority).

License requirements and conditions for the implementation of pharmaceutical activity are:

- a) the applicant for a license (licensee), acting on its own, by right of ownership or on other legal grounds should be equipped with equipment, facilities and appliances necessary for the licensed activity;
- b) compliance with the requirements of the technical reinforcement and equipment means the alarm and premises used for the implementation of pharmaceutical activity;
- c) compliance with rules governing the storage and handling of drugs based on their physical-chemical, pharmacological and toxicological properties, as well as with drugs, possessing flammable and explosive properties;
- d) ensuring quality standards for medicines in their possession, sale and manufacture;
- e) compliance with the rules of the wholesale and retail trade in drugs, as well as rules for the preparation of medicines in pharmacology;

f) the heads of organizations, wholesalers and pharmacology, whose work is directly related to the reception, storage, release, manufacture and disposal of medicines should have higher pharmaceutical education, professional experience of at least 3 years and a specialist certificate; pharmaceutical institutions specialists, involved directly in manufacture, storage, release and sales of medicines, should have higher or secondary pharmaceutical education and professional certification; professionals, working in wholesale pharmaceutical organizations, directly involved in receiving, storing and dispensing of medicines, should have higher or secondary pharmaceutical education and professional certification;

g) the advance professional training at least once in 5 years is required for all qualified employees, carrying out pharmaceutical activities

To obtain a license the company shall submit to the licensing authority the following documents:

- Application for a license, stating:
 - o The names and organizational-legal form, location of the entity, as well as the location of its geographically separate units and facilities used for the implementation of the licensed activity;
 - o Licensed activities (listing the work to be undertaken by the licensee);
- Copies of all legal documents and a certificate of state registration of the applicant's license;
- A copy of the certificate of applicant's license to the Tax Authority;
- A document confirming payment of license fee for consideration by the licensing authority an application for a license;
- A specialist certificate confirming compliance with the training manager of a legal entity, the head of the division of a legal entity licensed activity;
- Documents confirming the right of the applicant's license to use the premises for the licensed activity;
- Copies of documents confirming the applicant's employees receive a license or higher secondary pharmaceutical education;
- A copy of the conclusion from the sanitary-epidemiological department on the premises under the requirements for the implementation of the licensed activity.

All documents submitted for obtaining a license, shall be taken on an inventory, a copy of which indicating the date of receiving the documents the licensing authority handed to the license applicant.

It is not allowed to request other additional documents from the license applicant.

The Licensee is liable for false or distorted information. The licensing authority, during licensing process, has the right to verify compliance with the license applicant's requirements and conditions.

The licensing authority decides to grant or to refuse to grant the license within 60 days of receipt of the application with all necessary documents.

Validity of licenses for pharmaceutical activities is 5 years. In the case of loss of license the licensee has the right to duplicate it.

The authorities have a right of monitoring compliance with the license requirements and conditions. Scheduled and unscheduled inspections can take place.

2.4.3 Medical activity

Healthcare reform has influenced the procedure of medical activity licensing as well, having tightened the requirements to license holders' qualification, equipment facilities and selected accommodations.

Procedure for acquisition of license in medical activities area is stipulated in the Decree of the Russian Government No. 30 dated 22 January 2007 on Approval of the Regulation on Medical Activities Licensing.

Main requirements to be met by applicants are to submit the following documents to the licensing authority:

- a) copies of documents to confirm that the license applicant has, on an ownership or other legal basis, buildings, premises, equipment and other technical and material facilities required for medical activities;
- b) copies of documents to confirm education (post-graduate vocational education, training) and documents to confirm work experience of the legal entity director or deputy director;
- c) copies of documents to confirm education (post-graduate, further vocational education, training) of specialists that are license applicant staff members or are employed by the applicant on a legal basis for work (service) performance;
- d) copies of education certificates (post-graduate, further vocational education, training) and copies of documents to confirm solo trader work experience related to performance of work (services);
- e) copies of registration certificates and certificates of conformity for the used medical equipment;
- f) copies of documents to confirm education and skills of the license applicant employees who perform maintenance of medical equipment, or agreement with contractor licensed for this type of activities;
- g) copy of duly issued Sanitary and Epidemiological Inspection report verifying compliance of performed medical activities with the sanitary regulations.

In addition to the above listed documents, the licensing authority specifies a number of requirements for a license applicant and failure to comply with these requirements may result in dismissal of license.

These requirements include:

- availability of buildings, premises, equipment and medical equipment required for performance of work (services) complying with the specified requirements that are owned by the license applicant on an ownership or other legal basis;
- higher (secondary, in case of rendering paramedical work (services)) vocational (medical) education, post-graduate or additional vocational (medical) education and at least 5 years of work experience in the same occupation for the legal entity (license applicant) director, deputy director or department head responsible for licensing activities;
- higher (secondary, in case of rendering paramedical work (services)) vocational (medical) education, post-graduate or additional vocational (medical) education and at least 5 years of work experience in the same occupation for the solo trader (license applicant);

- specialists that are license applicant staff members or are employed by the applicant on other legal basis required for work (service) performance who have higher or secondary vocational (medical) education and specialist certificates according to the requirements and nature of performed work (services);
- skill training of the specialists performing work (services) at least once every five years;
- when performing medical activities the license applicant shall observe health technologies permitted for usage in the manner prescribed by the Russian Federation law;
- when performing medical activities the license applicant shall meet sanitary rules;
- p)when performing medical activities the license applicant shall ensure control of compliance of the medical work (services) quality with the specified requirements (standards);
- the license applicant shall meet duly approved rules for fee-for-service medicine;
- k) license applicant's employees shall include specialists who perform maintenance of medical equipment or the applicant shall have an agreement with a contractor licensed for such type of activities;
- l) accounting and reporting records kept by the license applicant during performance of medical activities.

Period of the license validity is determined as maximum, i.e. 5 years, that may be extended.

Roman Micaelyan, General Director of Arzumanov Consulting (Medical Licensing):

A choice of building is the most important stage at the beginning of the license issuing process. Premises where are you going to render medical services, must be on the first floor and up.

The legal status of the company is also very important: it should be a legal entity or a natural person. Legal entity has a wider range of possible medical services to render than a natural person in compliance with Russian legislation. After company registration and a premises choice you need to obtain permission for further licensing procedure from Rospotrebnadzor (Federal Supervision Agency for Customer Protection and Human Welfare) and Ministry of Emergency Situations. At the same time you should provide a list of potential specialists who will work at your clinic.

On 29 March 2010 St. Petersburg Healthcare Committee adopted an Instruction on administrative regulations concerned the procedure of medical activity licensing. All documents formed for obtaining of medical activity license are examined by Healthcare Committee on the regional level. But it cooperates with federal bodies.

Time of getting license is 3 month. But usually it gets 4-4,5 moths.

PART 3 SWEDISH EXPERIENCE OF DOING BUSINESS IN RUSSIA

Within the framework of the survey interviews with two Swedish companies working in the Russian market and with one Russian clinic which used to have Swedish ownership were carried out. Based on these interviews and other available materials we have summarized a list of recommendations for Swedish companies entering the Russian market.

- Way of making business has to be adjusted to the Russian market

Irina Sandin, Business Development Manager, Elekta Ltd: "The question is to find the right level because sometimes we invite American doctors who present more louder and brighter but that doesn't fit the local audience as it looks like a TV-show. ...we don't call international organization because when they come they start to teach Russian doctors some simple things. Sometimes it's necessary but it depends on how you present it. Russian doctors travel around the world, they know theoretically how it can work, maybe they don't know it practically, but they travel and have a good language so they can keep conversation and it will be interesting. ... but we also have regional centers where people have more routine work and are very busy to study new technologies. So we need to think how to make a presentation."

Agneta Ekblad, Development Director Eastern Europe, Carmel Pharma AB: "I'm adjusting some of the materials to fit. I've been fortunate to meet with a lot of peoples and I know how I can catch their interest. We have a lot of materials we use all over the world and I choose those pieces that I feel would be interesting for people I meet here."

Dr. Christoph C. Dengler, Lawyer and Translator for Russian, Mannheimer Swartling, heading the Pharmaceutical Group Russia: "Business is conducted a bit differently than in Western countries. It is more relationship driven and seems sometimes to be a bit less transparent. Due to stronger hierarchical structures it is important to deal with the decision makers. Otherwise the results achieved so far may be frustrated or changed. Be patient, at the beginning it takes a while to get a decision but the more the deadline draws near, the stronger grows the commitment to get things done."

- Don't hesitate to ask questions

Agneta Ekblad: "I'm not afraid of asking for help and I ask very frankly about things because if they don't want to answer they just don't answer. And I get answer to most of my questions... I had some thoughts about the Russian market coming to Russian hospitals that it can be more closed, not so open to show everything and talk about the procedures and problems. But they had been very, very open with everything. So that's really positive."

- To make business in Russia you need to be present here

Natalia Mironova, General director, Swedish Dental: "You need to keep one's finger on the pulse. As a manager I understand that sometimes you need to correct, to underline something and may be to promote the Swedish way of doing things."

Agneta Ekblad: "I stay one week every time I come. I try to use the time really effectively to see as much as I can."

Dr. Christoph C. Dengler: "For me it is vital to live and work here, to understand people better and develop contacts through intensive networking. A company should have at least one reliable person on the spot to conduct business who knows the mentality and language."

- **Be transparent and try to develop contacts with the local authorities as they can provide access to a wide range of public healthcare institutions**

Agneta Ekblad: "Swecare connections with the Health Committee in St. Petersburg have been extremely helpful for me actually. I don't know how I would manage in such a short time period to get into so many good hospitals and ... meet really influential people. ... I tried to contact some hospitals myself in English and you never get any kind of response on e-mails. And if you try to call hospitals and if you don't speak Russian it is really hard to reach the person that you are looking for. Usually you are disconnected by the operator because you can't communicate. So for the Swedish company I would say it would be impossible to do it without help from translators or the Health Committee."

Dr. Christoph C. Dengler: "In fact the city committees of St. Petersburg are eager to support us. We were able to organize within 24 hours a meeting between representatives of various committees and Western companies."

- **Cooperate with local companies while carrying out registration and certification procedures.**

Irina Sandin: "Our previous manager tried to do registration through the international body in Sweden and UK. And after 5-10 years it was still no license for Russia. The first license was acquired by our distributor in 5 months. So it was impressive for us."

Natalia Mironova: "First time we managed to receive a license in 3 months. However we had a challenging experience when we got to know that the premises we rented were juridical a part of a residential area. That was an obstacle of prolongation the license and the reason of selling the business to the Russian staff. Last time it took 9 months to prolong the license and I think it is a good result as we managed to do it ourselves without contracting a specialized company."

Agneta Ekblad: "We have found a right way: to get the registration as soon as possible we had to get the Russian agency. They do all the paper work in order and also make sure of all the tests of the product. That was already done and the papers were sent in. So it's likely we'll have a certification within the period of three months"

- **Develop your own contact network**

Irina Sandin: "Starting from 90s, Russian surgeons were coming to international meetings and we pointed one specific Russian institutions like Burdenko institute in Moscow or St. Petersburg Institute of brain with whom we managed to develop very strong partnership.

We do a lot of work, I'm involved in the issues of the clinical support and technical support, including presentations about different products, for example the therapy line, that includes the whole complex of IT-products, high-tech products, diagnostic-products, so we obviously have a lot of specialists. ...I personally know a lot of doctors and we invite them to our factory and to the international clinical courses. So we are operating on the clinical level and the level of the Ministry of health if necessary."

Dr. Christoph C. Dengler: "As said before, Russia is a relationship driven country and therefore network is a key factor to success. It is an investment in terms of time but it is worth it."

- **Find a reliable partner/distributor**

Irina Sandin: "We started with choosing a right distributor. We took another way than other big companies in Russia (for example General Electric or Philips), which have different distributors in each area. It's logical as they have their representation here so

they can control. For us it was no way: we needed a strong partner in Russia who could put their own money to develop marketing etc...

Last year 3 of 7 machines sold in Russia were Elektas. Even when other companies were present in the country for 20 years and we - only for 5. The reason is that our distributor is the only company who has all the required licenses to work with this kind of equipment and has the biggest service group in Russia,"

Agneta Ekblad: "I'm trying to find a distributor not too big and not too small so that our product can still get attention. I think to go with a distributor would be the best because they will make warehousing. It would be very difficult for us to sell to the Russian market without warehousing. Everything needs to be in place here."

According to the Business network Switzerland, there are mainly two options how to work in Russia. You can cooperate with a local importer or act as your own importer and wholesaler. Usually, it is easier to start your business with the support of a local importer, as he can do all the certification and registration work for you, which costs a lot if you are not introduced in the market.

Another positive point of working with the Russian partner is in the specific understanding of the Russian market and the healthcare system. Local distributors are contacting the clients directly and can also arrange information support. It is an important advantage if your distributor is already working not only with private clients but also with state organizations and hospitals. Of course, conducting business through your own importing company has also many advantages. You can decide your own selling strategy; it is easier to control the marketing and the distribution of your product. But it is absolutely necessary to have very experienced staff that has been working in this business for years. Besides, one should not underestimate the administrative and cultural hurdles which might be faced by foreign companies that try to enter the Russian market on their own.

A good strategy to combine the advantages of both ways can be the establishment of a branch office which can support the importer in the marketing and the client acquiring process.

Dr. Christoph C. Dengler: "Regardless of how you work together, it is important to choose a responsible partner whom you can trust and who conducts business according to your standards. A lot of companies start with a distributor and establish at later stages a joint venture or even open their own rep offices. With respect to the first two forms of penetrating the Russian market, make sure that you have an exit scenario with your partner at your will which means you have either a termination possibility if the Russian partner does not perform as agreed, or that you have the necessary voting rights (more than 50 percent of the shares or even 67 percent), e.g. in order to appoint or dismiss the general director etc. As lawyer we see sometimes joint ventures in a deadlock, as the parties cannot agree how to go on. Therefore I would go that far and recommend you to rather open your own rep office if the performance of your product justifies such a step."

- **Consult with a legal company you trust regarding signing the contracts in Russia**

Natalia Mironova: I will highly recommend obtaining a good legal background for working here from respectful legal consultants or other partners who have been working here. That is very important for understanding the market and making affairs here for a long period.

Dr. Christoph C. Dengler: “In our view it is crucial to have a high quality check of your agreements even if it takes longer. No deal and no agreement are sometimes better than a bad deal with an unbalanced agreement to your detriment by which you are bound.”

- **Don't be afraid of the new market as it provides new opportunities**

Agneta Ekblad: I think the hardest is actually to get to Russia. It's very different to me because I have to plan everything ahead (visa etc). To get to the person even if you know the person and the person speaks English through all the layers of the operators - that's very hard. You need assistance to come in... It is difficult because of the language barrier. As for the legislation... I see it on the most of the markets all the time: the guidelines and recommendations from the Health ministry will be changed. But it takes time, it will happen maybe after a couple of years, maybe after 5-7 years, but we have to start already now”.

Irina Sandin: “This huge potential and needs in oncology from the clinical and customers point of view – obviously it is a valuable market for us. When we came here such equipment didn't work it was lack of service, lack of experience, lack of specialists and everybody was scared to use this kind of equipment. Obviously it was a bad reputation generally about linear accelerator: it's not for Russia, it is better to take simple cheap equipment than to take this big and expensive one, that doesn't work and so on. So we needed to fight and this could be used to position us because we could say we would be different. But of course it was very difficult because people do not take easily such complicated equipment.”

Natalia Mironova: “Our clinic was opened in 1998 by a Swedish doctor and a Swedish businessman. There was almost no competition at that time and we could provide exclusive services of a Swedish dentist in Russia. The profit was appr. 25-30%. However due to increasing competition it could not last forever.

Swedish brand is still very winning and attractive in Russia. Everyone knows here such brands like IKEA, VOLVO etc. Swedish means 'uncompromised qualitative' in Russia. I think Swedish businessmen are sometimes scared of making business in Russia as they are already got accustomed to working in very transparent and regulated conditions. Here the legislation and the whole system are not finally developed yet, so you need to take the best from this situation.”

CONCLUSIONS

The Soviet healthcare system was centralized, integrated, hierarchically organized and wholly financed from general government revenues. Healthcare services were (in principle, at least) provided free to all citizens, and all health personnel were state employees. The system placed enormous emphasis on the control of epidemics and infectious diseases. This contributed to the development of a large and effective public health (*san-epid*) network, but the determination to isolate infected persons also led to overprovision of hospital beds, which contributed over time to an imbalance in the overall structure of healthcare provision. On the whole, the Soviet system tended to neglect primary care, apart from public health, and to place too much emphasis on specialist and hospital care.

The structure of the Soviet system, which specified the length of treatment for every disease, often caused people suffering from relatively minor ailments such as influenza to be hospitalized. The result was a serious overcrowding problem in hospitals despite the large number of beds available. Patients also preferred hospital treatment because hospitals were better equipped than clinics. In the 1980s, the Soviet Union was first in the world in the ratio of hospital beds to population.

Since 1991, the centerpiece of healthcare reform in the Russian Federation has been the transition from an integrated, hierarchical model of healthcare provision to a more decentralized, contested and insurance-based system of public healthcare.

According to the Russian Healthcare Development Concept 2020, the reduction of the population which has begun in 1992 is proceeding. However rates of population decrease in the last years have essentially decreased - from 700 thousand persons annually in 2000-2005 to 213 thousand persons in 2007. For 10 months of 2008 the factor of a natural decline of the population reached 2,7 per 1000 while for the relevant period of 2007 it reached as much as 3,4.

Russian population size in 2008 was about 141,9 million people which is 116,6 thousand people less than in 2007.

Decrease in rates of reduction of population is ensured mainly by increase of birth rate and death rate decrease. The indicator of maternal mortality per 100 000 born in 2007 has decreased by 7,2% compared to 2006. The indicator of infant mortality per 1 000 born live in 2007 has decreased on 7,8% compared to 2006

In 2006, for the first time for the last 7 years, predicted life expectancy of the population of the Russian Federation has started to increase.

The major indicator of efficiency of public health services of any country is an average life expectancy of the persons, suffering chronic diseases. In Russia it makes up 12 years and in the EU countries it is 18—20 years.

In 2009 the revenues of the Russian healthcare organizations constituted 391 billion RUR, which is 10% higher than in 2008. The volume of provided medical services decreased from 812 to 770 million. As you can see the revenues growth was determined only by price increase. Starting from 2000 the price index of medical services has been always kept ahead the inflation rate. The prices increase was introduced because of property appreciation, price increase on drugs, equipment and salaries growth.

The average volume increase of the St. Petersburg medical services market grew in 2006-2008 by 20% per year and constituted 28,4 billion RUR in 2008. It is 6,1% of the

Russian market. In 2009 due to economic crisis it St. Petersburg medical services market decreased by 26,9%.²¹

St. Petersburg is characterized by high prices for medical services: For example when the average price for medical services in Russia in 2008 was 483 RUR, the price in St. Petersburg was 793,6 RUR. The income of medical staff in St. Petersburg is 1,5 times higher than the average level in Russia. On the other hand St. Petersburg remains less 'expensive' than Moscow meaning the price of medical services.

Alexander Mironenko, Head of St. Petersburg Regional Branch of All Russian Medical Association, Deputy Director of the St. Petersburg Institute of Ear, Throat, Nose and Speech, Honored Doctor of the Russian Federation:

St. Petersburg healthcare system is very well established but may be less financed per patient as in Moscow or some other oil and gas regions. But the city has a good R&D base and modern equipment as well as wide international contacts for experience exchange. A lot of hospitals are under reconstruction now.

Summarizing the trends of the healthcare system development in Russia a list of topics recommended for further analysis was prepared:

– The development of the primary healthcare system in Russia

The Russian government has announced the development of the primary healthcare to be among the priorities. Despite the developed network of the out-patient-polyclinic facilities, the existing system of the primary care is not capable to satisfy requirement of the population and remain overloaded and ineffective. It is partly connected with a large number of persons, 'attached' to 1 outpatient district (in big cities – 1800-2500 people per district, in fact – up to 4000 people) that transforms functions of the doctor to the operator writing the prescription on drugs.

Long waiting time of the medical appointment, the inconvenient schedule of work of the state and municipal outpatient facilities (mainly at week-days) makes it almost not available for the working population

Low efficiency of preventive activities of primary care, absence of system of an outpatient recovery and home nursing, as well as imperfection of the organization of work of emergency services have led to fact that the inpatient departments have become the basic level in Russian public healthcare system.

During the last years the government has invested a lot in the primary sector incl. staff training, equipment, salaries growth etc.

Alexander Golyshev, Chief Doctor of the Children's Clinical Hospital №5 named after N.F. Filatov:

The National project "Health" has invested a lot in the primary care, mainly in salary increase and providing of new equipment. For example, our hospital doesn't have such equipment as some policlinics. However the hospitalization rate has increased by 30%.

²¹ Analysis of the healthcare market in Russia and forecast 2011-2014. (BusinesStat, 2010)

The potential for private Swedish companies for entering the Russian market and the demand for quality primary care services among the citizens should be studied in a more specific way.

– Self-regulatory organizations in healthcare (SRO)

SRO is a non-governmental organization that exercises some degree of regulatory authority over an industry or profession. The regulatory authority could be applied in addition to some form of government regulation, or it could fill the vacuum of an absence of government oversight and regulation. The priority is to protect investors through the establishment of rules that promote ethics and equality, provide quality control of education and medical services.

In Russia medical SROs were first established in the beginning of the 20 century but were rolled down after the USSR was formed. The first attempts to get them back were made in 1993 and 1996 when Russian medical association and Russian medical society were formed. Unfortunately they didn't succeed as there was a too strong control from the government.

In 2007 the government has adopted a Federal law on self-regulatory organizations (SRO). The idea was taken from the American model of professional associations. A good example of SRO in the in healthcare is the American Medical Association which sets rules for ethics, conflicts, disciplinary action, and accreditation in medicine.

The first sector which has fully introduced SROs in Russia was construction. On 1 January 2010 the construction sector in Russia adopted a new regulating system that replaced licensing with self-regulation, i.e. construction business in Russia must be performed by the companies exclusively on the grounds of admission certificates received from construction SROs. It means that all companies who perform construction, reconstruction or extensive renovation work or who contribute to the safety of major construction work need to join a SRO (there are several construction SROs already established in Russia). SROs in the transportation and educational spheres have also already been founded in Russia.

In autumn 2009 the head of the healthcare committee of the Public Chamber has announce an importance of creation the National Medical Chamber based on the principles of SRO. However the created National Medical Chamber in its current form cannot be considered as SRO because of many criteria, for example possibility of charring out commercial activities which is forbidden for a SRO.

Larisa Petrenko, General Director of the Non-profit partnership for the development of the healthcare system "Professional Medicine":

The main objective of healthcare SROs will be to secure high medical standards of professional healthcare system introducing quality control instruments. The state grants some of its powers to professional associations.

– Autonomous and budgetary organizations in the healthcare sector

In the end of 2006 the Federal law on Autonomous organizations was adopted. Autonomous organizations is a non-commercial organization, established by the Russian Federation, a subject of the Russian Federation or a municipality for the reasons of providing public services and charring out activities stipulated by the Russian legislation in the spheres of science, education, healthcare, culture, social security, employment of population and sport. On the other hand the law contains a number of restrictions on transferring the organization form of public healthcare facilities to the

form of autonomous organizations. From 2011 these restrictions are planned to be eliminated.

Until the end of 2010 a new law On Budgetary Organizations is going to be introduced. According to the new law all public financed organizations will be divided into official (internal affairs, military organizations, out-patient psychiatric facility, infections hospitals etc) and budgetary (the majority) which will be financed only through the state order of services. Budgetary organizations will be granted a right of providing services on commercial basis.

Oleg Sergeev, Chairman of the Permanent Committee on Healthcare and Environment of the St. Petersburg Legislative Assembly:

The idea is to decrease a financial burden of the social and healthcare services on the budgets. Now it is very hard to forecast how a new law will influence the public healthcare organizations. Anyway they will acquire more flexibility in financial management

Alexander Golyshev, Chief Doctor of the Children's Clinical Hospital №5 named after N.F. Filatov:

If public healthcare providers acquire more flexibility in financial spending it will also give us new opportunities for cooperation with international partners. I think if public institutions have a right for investments projects it will be very interesting for the

- Development of standards of medical services in Russia and one-channel financing system

According to the prime-minister Vladimir Putin the Government plans to increase the medical insurance tax from 3,1% to 5.1%. This will provide extra 460 billion RUB to the OMS budget. The government is also planning to give all citizens a possibility to choose insurance company themselves not via an employer. This year a new bill on Mandatory Medical Insurance is planned to be introduced, which will include measures on transfer to one-channel insurance system. The OMS fund is expected to become the only financing resource of public healthcare institutions in Russia. A transfer to the single-channel financing system with higher tariffs will provide new opportunities for public and private institutions.

- Development of public-private partnership (PPP)

In December 2009 the St. Petersburg Legislative Assembly has adopted a Law On Participation of St. Petersburg in public-private partnerships (PPP). This Law is related to the Federal Law on Concession Agreements (2006). According to the Russian legislation PPP is a mutual beneficial cooperation with Russian or foreign legal body or natural person or a group of legal bodies in the implementation of socially significant projects by means of conducting agreements, incl. concession ones.

The St. Petersburg law stated priority areas for PPP: transport infrastructure, municipal infrastructure (incl. waste management), energy supply, communications, healthcare, education, culture, social services, tourism and sport.

Since 2009 the project of reconstruction of Children hospital N5 is the mostly discussed PPP project in the city. In the end of 2009 the project has received positive remarks from the Head of the Healthcare Committee of the St. Petersburg Legislative Assembly Oleg Sergeev and vice-governors Yuriy Molchanov and Ludmila Kostkina. In May 2010 the St. Petersburg Healthcare Committee signed the recommendation of the project for further implementation by the City of St. Petersburg

This project can become the first PPP in healthcare in St. Petersburg. However it will not be the first in Russia as AVA-Peter clinic has already started PPP in Kazan. It is a construction of the perinatal center with 51% of private investments (appr. 13,4 billion USD). The rest is owned by the government of the City of Kazan which provided a lot and a building. According to some specialists the success of the project was determined by a big interest of the city authorities in the implementation of such a socially significant project.

– Development of Import Regulations

Customs regulations are one of the first and main concerns of companies doing business in the Russian Federation. In general the classical instruments to control imports and exports, which are regulated by the Federal Law On Principles of State Regulation of Foreign Trade Activity are used. Although most products can be freely imported into and exported from Russia, some products such as radioactive materials, narcotics and psychotropic substances require a license. In some areas imports or exports are subject to quotas and other restrictions. As the requirements are continuously changing we can also recommend paying extra attention on this issue.

In conclusion it is important to emphasize that with a growing income of consumers and an increasing funding of the government, the perspective for healthcare providers and medical producers are generally very positive in Russia. However, due to the high level of state regulation, bureaucracy and the lack of transparency in this sector, it is really crucial to have either a reliable partner who has been working for a long time in the healthcare sector or a very experienced own staff. In general, the personal contacts to potential clients and decision makers are likely to take much more time than in other European countries.

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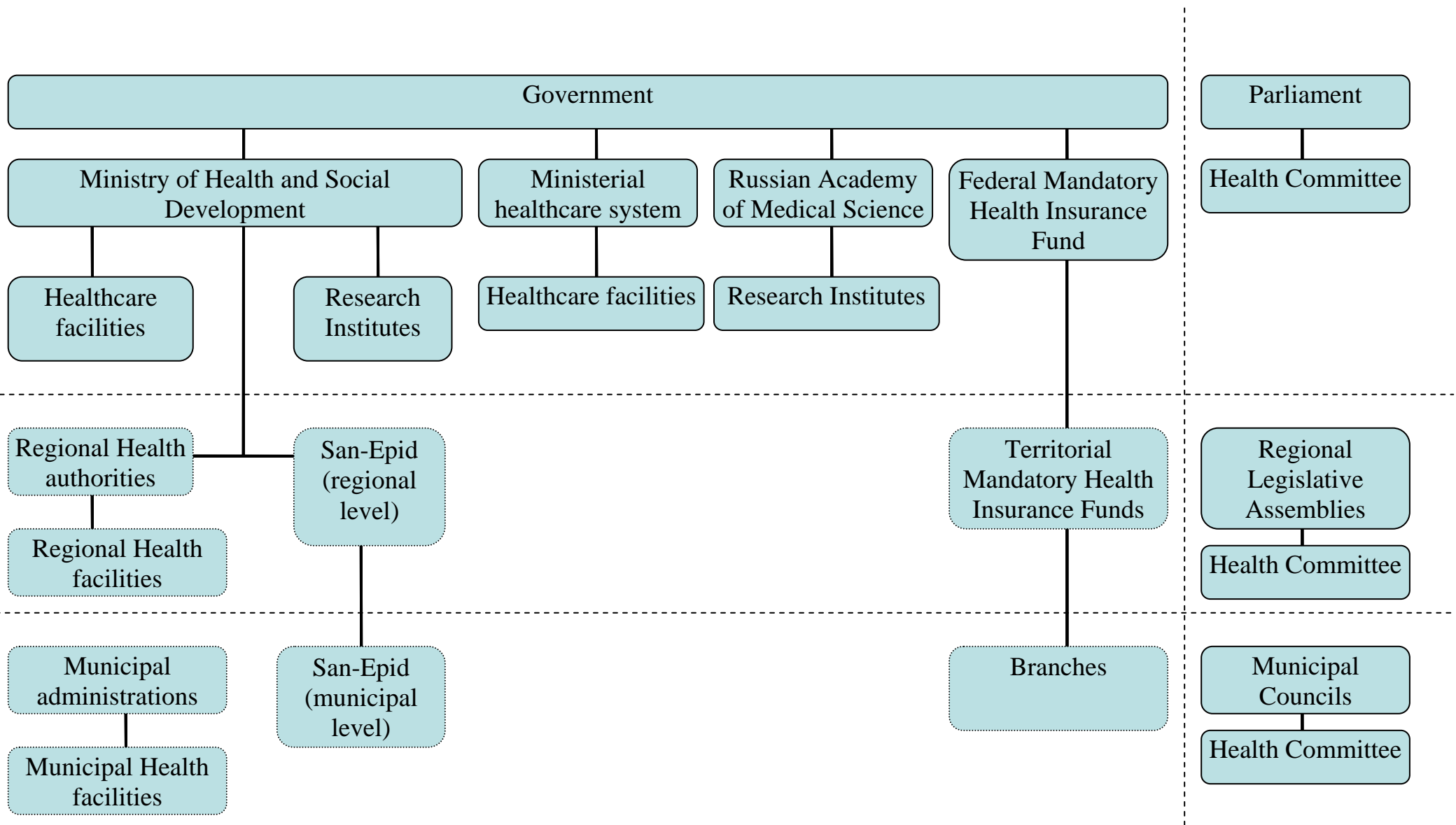
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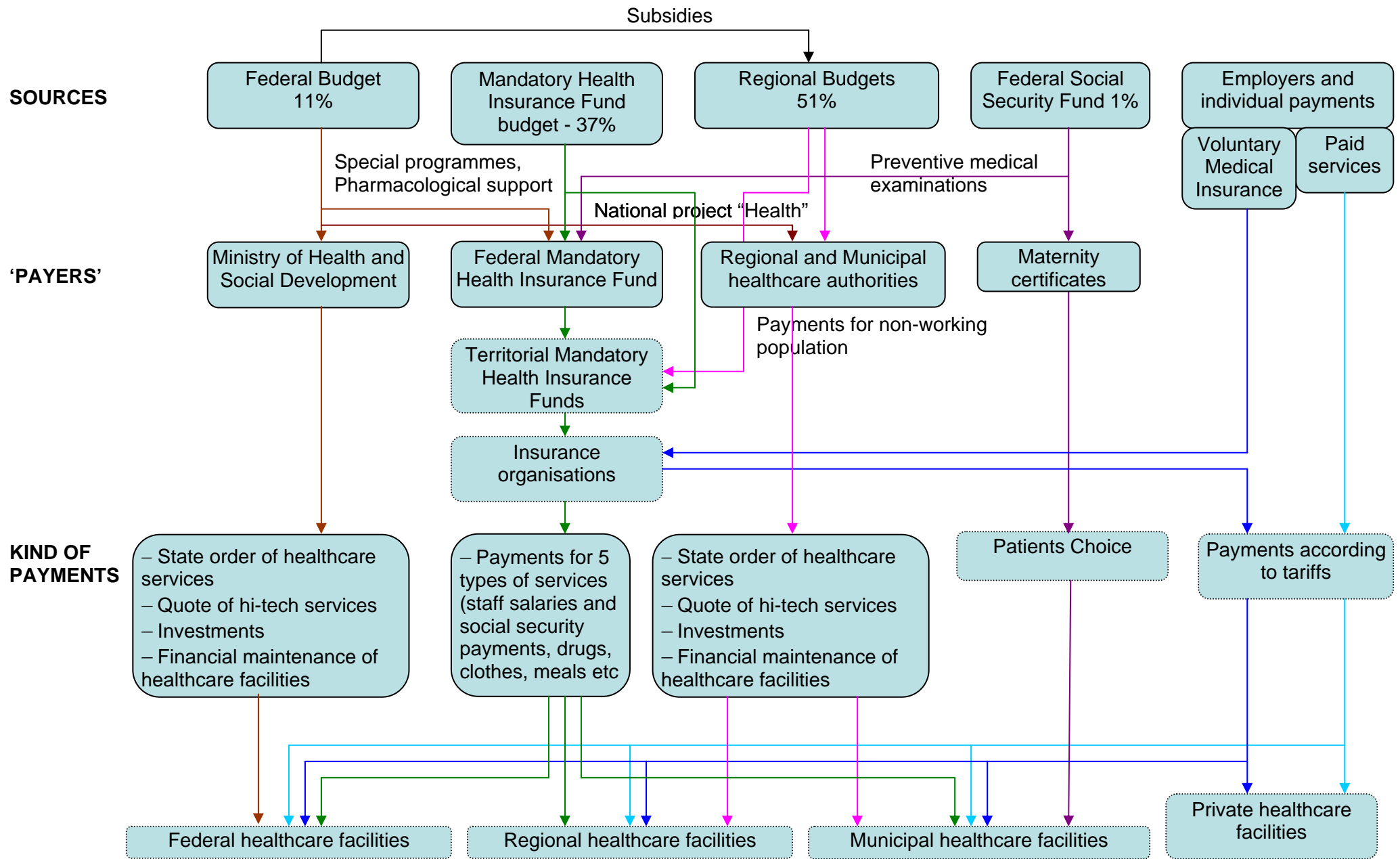
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Appendix 1 Organisation Structure of the Healthcare system in Russia



Appendix 2 Financing of Healthcare services in Russia (based on the Healthcare Development Concept of the Russian Federation until 2020)

Appendix 3 List of Documents for Registration of Medical Devices and Equipment

1. A letter from the manufacturer with the company's letterhead testifying their intent to register a product/products. The letter should be in the manufacturer's native language with a Russian translation.
2. An application for registration (re-registration) of a medical device/equipment written on the Applicant's letter-head. The application should contain, if necessary, the exact and complete description of the product components. The application letter should either be in Russian or followed by a Russian translation.
3. A Power of Attorney to an authorized representative for conducting registration. It should be given to a legal entity (addressed to the head of the company) and notarized in compliance with the current legislation. The Power of Attorney should be legalized in the country of the manufacturer's origin. If the country is part of the Hague Convention of 1961, the application should have a special stamp called Apostil. The Power of Attorney should state that the manufacturer entrusts the Applicant to conduct the registration of a medical device/equipment, sign a consultative and expert works contract and receive the registration certificate.
4. The information on the medical device/equipment. It should contain a brief description of its usage as well as information on when it was developed, launched into production and which world markets it is supplied to. The document should be prepared in Russian or have a Russian translation.
5. A picture of the medical device/equipment (not smaller than 130x180 millimeters). The picture should reflect a detailed view of the device and its components.
6. Advertising illustrative materials and printed matter. Can be provided in a foreign language.

Appendix 4 List of Documents for Registration of Foreign Drug Agents

1. Letter of attorney certified by apostil from manufacturer to a legal entity, specializing on drug agents registration.
2. Certificate about free realization (or pharmaceutical product certificate), certified by apostil (Original or notarized copy).
3. License to production issued by manufacturer and certified by apostil (notarized copy).
4. GMP certificate, certified by apostil (Original or notarized copy).
5. Registration certificate issued in the producer country and certified by apostil of the company.
6. Analyze certificates for the ready product and for active material, certified by the seal of the company.
7. If the certificate for trademark is available - copy of registration certificate for trademark in the Russian Federation, certified by the seal of the company.
8. Information on drug agent registration in other countries (in what countries they were registered, during what period), certified by the seal of the company, (test reports).
9. Concise description of the engineering procedure, certified by the seal of the company.
10. Complete description of quantitative and qualitative analyses methods (with reference on pharmacopoeia + specification).
11. Data concerning stability on the agent samples of no less than three series, confirming expiration date, declared in all registered kinds of primary package.
12. Pictures of specters and chromatograms.
13. Report on research of pharmacological (specific) activity, motivating all the indications for use, mentioned in the instruction.
14. Report on research of toxicity (acute, sub acute, sub chronic, chronic toxicity).
15. Report on research of specific kinds of action (carcinogenicity, mutagens, teratogenic action, embryotoxicity, allergenic and a local-irritating qualities etc.).
16. Clinical tests reports.
17. Data concerning use of the agent in the clinic and publications, following its registration (publications copies) (only concerning the agent produced by the company).
18. Data concerning bioequivalence (for tablets, capsules, dry powder for preparing suspensions).
19. Information on side effects in comparison with the analogous agents with the similar effect.
20. Medical application instructions: samples and packing.
21. Information on the material, used for wrapping the agent: certificates for packing materials packaging, confirming possibility of their use for medical purposes, certified by the seal of the company.

22. Colors samples of inner and outer packing (in the source and Russian languages).
23. Standard samples of active substance, necessary for quality control.
24. Working and standard samples of the drug agent for carrying out of obligatory quality assessment of the samples of drug agents, declared for the state registration.