

Biotechnology in Russia: Why is it not a success story?

According to President Medvedev 2009 'By and large, our industry continues to make the same outdated products and, as a rule, imported generics from substances bought abroad. There is practically no work to create original medicines and technologies.'...'We must begin the modernisation and technological upgrading of our entire industrial sector. I see this as a question of our country's survival in the modern world'... 'These are the key tasks for placing Russia on a new technological level and making it a global leader'.

Many states including Russia see biotechnology and its commercialization as a key driver for their future growth. The biotechnology area is characterized by being a very knowledge-intensive activity where there is increasing global competition for know-how. Russia had a very good historical base of R&D and knowhow in biotechnology from the previous Soviet military programme. There have been many attempts since 2000 to revive the Russian biotechnology industry not least in 2005 but without much success. In 2009 there were again very ambitious programmes and strategies developed as well as techno-parks for the development of the biotechnology and pharmaceuticals industry up to 2020. It has also been announced by President Medvedev the creation of a Russian equivalent to 'Silicon Valley' to include R&D also in biotechnology outside Moscow. There have been many such grand plans but so far they have not been very successful and the question for this study was if it would be different this time? Why are scientists still leaving Russia and foreign investors still hesitating to invest in Russian biotechnology or pharmaceuticals? Why is Russia still not able to compete on the global biotechnology market and is ranked only as number 70 in the world? The current problems and prospects for the biotechnology and pharmaceuticals industries are analysed.

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Picture on front cover: Russian Prime Minister Vladimir Putin seen during a visit to Binnopharm pharmaceutical and biotechnology research and production center in Zelenograd, October 9, 2009. (Source RIA Novosti)

Titel Varför är inte rysk bioteknik en

framgångssaga?

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Summary

During the Cold War there was rapid growth in the area of biotechnology, not least for military applications, in the former Soviet Union. During the presidency of Boris Yeltsin in the Russian Federation, 1991–1999, the national biotechnology industry was privatized, which led to a near-collapse of state support for research and development in biotechnology. This resulted in financial difficulties for many companies and emigration of many leading scientists. In turn, to a great extent, imported biotechnology and pharmaceutical products replaced the domestically produced.

In the process of economic modernization of Russian industry, biotechnology has been given higher priority since 2005. Funding for Russian biotech research was, however, estimated at only \$0.04 billion per year while for China it was \$1 billion and for the U.S. more than \$10 billion. In addition, Russia ranked globally as only number 70 in the biotechnology area. Nevertheless, there are reasons for optimism about the future development of the Russian biotech industry, and there are more than 1000 institutes and organizations with, in many cases, highly qualified personnel conducting biotechnology research. The Russian Government and private industry are recognizing the urgent need for reforms to improve the legal and economic environment for the biotechnology industry in order for it to become more competitive.

To promote and improve coordination within the biotechnology sector, an ambitious National Program for the Development of Biotechnology 2006–2015 was developed, followed by the Development Strategy for the Biotechnology Industry in Russia 2010–2020. Regional biotechnology programmes have been developed and implemented in Kirov, Saratov, and Tomsk. Associations such as

the Russian Society of Biotechnologists and the Union of Enterprises of the Biotechnology Industry played an important role in promoting biotechnology. It is also important to promote international cooperation and open up the market for foreign investment in order for Russia to make progress in the areas of biotechnology and pharmaceuticals. It was estimated that Russian biotechnology could grow by 25–30 per cent per year, which was much faster than the rate of growth of the pharmaceuticals industry, of 10–12 per cent per year. The growth sectors for Russian biotechnology were pharmaceuticals, dietary supplements, cosmetics, agriculture, food processing, and environmental technology.

The government had emphasized that there was a need for a new relationship between research and business, including strengthening the innovation system. At the highest political level it had also been recognized that there was a need for Russia to produce its own drugs and that the present gap between research and commercialization must be bridged. The domestic biotechnology pharmaceuticals manufacturers had made too limited progress towards greater quality and compliance with international GMP (Good Manufacturing Practice) standards. The Russian pharmaceuticals market was one of the fastest-growing and the eleventh-largest in the world. The government set its ambitions high in that by 2020 Russia should become the fifth leading economy in the world, which was not very realistic. The ambitions for the development of biotechnology until 2020 were also set very high and could only be reached if extraordinary measures were taken and sufficient funding could be provided. Looking back at the difficulties Russia has had so far in promoting a competitive biotechnology and pharmaceuticals industry, the chances for success with these new plans are bleak.

1 Introduction

The development of biotechnology is one of the most dynamic and rapidly developing areas of science and technology. There are great potential benefits and possibilities in many areas: for health, new materials, chemical processing, alternative fuels, improved agriculture and food, as well as in the area of environmental protection. Biotechnology can be used as a good indicator of a state's international competitiveness in a high-technology and knowledgeintensive area. How successful is a state in transforming the results from research and development (R&D) into commercially competitive products in a highly globalized area such as biotechnology and pharmaceuticals? Russia has had a large and well developed industry and an R&D complex in biotechnology from the Soviet period, largely driven by military priorities and by the militaryindustrial complex. The question for this study is how Russia has managed to convert this knowledge base and then to develop it further in the area of civil biotechnology since the collapse of the Soviet Union. This will provide a better insight into how Russia is able to handle other R&D-intensive new and emerging technologies. In the biotechnology area there was a very good base in the form of know-how and industrial capacity to build on. How is Russia competing in the global market in this area and which are the future prospects for Russian biotechnology? A previous study focused on the conversion of the former Soviet biological weapons complex and former weapons scientists. 1 It described and analysed the international efforts to engage and promote so-called threat reduction activities and programmes in Russia and the former Soviet republics. This report will thus not cover this in detail.

1.1 Aims of the Study and Outline of its Structure

This study was initiated in order to evaluate and to monitor the so-called 'revival' of the Russian biotechnology industry. The aims of the study were to analyse the growth and development of Russian modern biotechnology as a basis for discussing the future prospects for biotechnological and pharmaceutical industrial applications.² To achieve this several aspects were taken into account. The study was to:

 Review the historical background to explain how Russian biotechnology has grown based on a long scientific history and the problems science

¹ Roffey, Roger (2008) EU–Russian Partnership to Reduce Bio-Threats and Fight Disease Outbreaks, Report FOI-R--2493--SE, March 2008 (Stockholm, FOI).

² Part of the material used for this study was collected and analysed by Kristina S. Westerdahl, FOI Defence Analysis, Stockholm, during spring 2007.

experienced during the Stalin era. Examine how leading scientists convinced the military to invest heavily in biotechnology as a means to promote the biological sciences, which resulted in the military being the driving force for developing biotechnology in the Soviet Union for a long time.

- Look at how the transition took place from military to market economic priorities.
- Describe the government's intentions and priorities as seen in statements and different programmes.
- Discuss why Russian biotechnology has not so far been more successful.
- Describe and analyse the present situation for industrial applications of biotechnology, including for the pharmaceuticals industry. One of the most important drivers for the developments in biotechnology is to find treatments for diseases and develop pharmaceutical preparations. This means that biotechnology R&D is also crucial for the pharmaceuticals industry.
- Discuss the future prospects for Russian biotechnology.

Chapter 1 gives an introduction to the study, presents its aims and gives a brief overview of biotechnology.

Chapter 2 explains some aspects of the historical development of Russian biotechnology so as to give the reader a better understanding of its situation today. The history of the development of biotechnology in Russia is unique and has to be taken into account when assessing current achievements and potential future prospects. Science experienced significant difficulties in the area of genetics during the Stalin era, during which many scientists were prosecuted. To be able to leave this period behind, leading scientists convinced the military that the Soviet Union needed to invest heavily in the new biotechnologies, including genetic engineering, in order to catch up with the West.

Chapter 3 describes the current situation concerning the defence aspects of biotechnology R&D so as to cast light on its role in the national revival of Russian biotechnology and to put it in the perspective of the previous weapons programme.

Chapter 4 describes how international cooperative threat reduction programmes were initiated in order to convert former weapons institutes and scientists and initiate activities aimed at developing civilian and non-military biotechnology. This is also important background as during the 1990s these programmes had financed much of Russia's fundamental research in biotechnology during a period when the state support from the Russian Government was very much reduced.

Chapter 5 describes how in biotechnology growing cooperation between the European Union (EU) and Russia as partners is taking the place of technical assistance. International cooperation will be crucial for the further development of Russian biotechnology and for making it more internationally competitive.

Chapter 6 briefly describes the Russian innovation system and its development so as to give a better understanding of how research in biotechnology is funded and the government's priorities.

Chapter 7 discusses some scientific aspects of the development of biotechnology in Russia.

Chapter 8 gives an overview of the biotechnology market in Russia and how it has developed since the collapse of the Soviet Union.

Chapter 9 presents the national non-governmental and governmental initiatives and programmes in the area of biotechnology in order to give a picture of the national priorities in biotechnology.

Chapter 10 describes more in detail the major plans for investment being made in large-scale production of biofuels. The aim is to produce very large quantities using biotechnology so as to cover both domestic needs and exports to Europe.

Chapter 11 gives some more details concerning priorities in the area of fighting infectious diseases, as this also has implications for defence applications.

Chapter 12 presents the developments in the pharmaceuticals industry with a focus on the applications of biotechnology. One issue is whether a competitive domestic pharmaceuticals industry can be achieved through government initiatives.

Chapter 13 summarizes and discusses trends in Russian biotechnology based on the findings of the study and presents some conclusions.

The **appendices** give some more detailed information on the types of R&D being carried out at some leading institutes and companies. These also include lists of critical technologies and references.

One of the major trends shaping the new security environment is the global diffusion of knowledge in the life sciences,³ for example, in biotechnology. Life sciences and biotechnology are recognized motors driving the knowledge-based so-called bio economy. Many states today see biotechnology and its commercialization as a key driver for future growth. As a result these countries are investing heavily in promoting domestic developments and aiming to attract foreign investment and partnerships. Countries like India and China are making major progress in the area of biotechnology as well as many Western countries

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³ Life science is the natural science concerned with the study of life and living organisms, such as biology, botany, medicine, microbiology, physiology, biochemistry, or ecology.

(for information on the Russian–Indian cooperation in biotechnology see Appendix 3).⁴ It is thus not surprising that Russia is striving to develop its activities and industrial capabilities further in the biotechnology area. One aspect of globalization is that breakthroughs in biotechnology are made in almost any country and not restricted to Western countries. Another aspect is that both R&D in this area and the biotechnology industry are becoming more global, and the industry is no longer so much a national industry as it was before. Today knowledge is the most important asset in this area. The biotechnology area is characterized by being a very knowledge-intensive activity where there is increasing global competition for know-how.⁵ Large investments and research teams are required to carry out cutting-edge research in this area. As the commercial interest in the area increases, more R&D is being carried out for commercial benefits, and ongoing activities are becoming correspondingly less transparent. This will make it more difficult to monitor the dual uses and potential misuses of biotechnology.

Historically, biotechnology was a priority area for the Soviet governments but the military was the driving force for its development. For example, it took certain specific measures in 2005 which resulted in an annual growth in sales value of around 30 per cent in this area. In the same year the lower house of the Russian Parliament, the State Duma, appointed an expert committee on industrial biotechnology, and it also approved a national biotechnology programme, The Development of the Biotechnology Industry 2006–2015, with a proposed total budget of \$5.2 billion (150 000 million roubles).⁶ A programme was approved for the period 2007–2011 concerning socially important diseases which includes diabetes, sexually transmitted diseases, tuberculosis and hepatitis, and vaccination. There was also a national programme for the development of nanotechnology from 2006 where priority was given to combinations of biotechnology and nanotechnology. In recent years, the Russian Government has shown an increasing interest in the biotechnology area and in promoting research. As part of its economic modernization, the government is giving special attention to biotechnology development. During 2009 the Development Strategy for the Biotechnology Industry in Russia 2010-2020 was elaborated.

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⁴ Epstein, Gerald (2005) *Global Evolution of Dual-Use Biotechnology: A report of the project on Technology Futures and Global Power, Wealth and Conflict* (Washington, DC, Center for Strategic and International Studies).

⁵ OECD (2006) *The Bioeconomy to 2030: Designing a policy agenda* (Paris, Organisation for Economic Co-operation and Development, Futures Program).

⁶ Russian Society of Biotechnologists (2005) *National Program, Biotechnology in the Russian Federation, 2006–2015, Based on Public-Private Partnership*, Russian Society of Biotechnologists, on the Internet: http://bioros.tmweb.ru/papers-society/programma_razvitia.doc (retrieved 24 February 2009).

⁷ Frost and Sullivan Research Service, 'Country Industry Forecast: Political and policy analysis for the Russian healthcare industry', on the Internet: http://www.frost.com/prod/servlet/report-brochure.pag?id=4H80-01-00-00-00 (retrieved 23 February 2009).

Then in October 2009 the Duma had a special hearing based on this to discuss how to develop the Russian biotechnology industry further.

Biotechnology was also referred to in the new Russian National Security Strategy approved in May 2009. The threats referred to included, the world financial crisis; competition over scarce resources like raw materials, energy, water and food; crime and corruption; and health problems such as new large-scale epidemics and the problems of AIDS, tuberculosis (TB), drug addiction and alcoholism. The main ways to counter them included the protection of human rights by judicial and legislative means, developing the pharmaceuticals industry and the health care system, guaranteeing food security by using biotechnology and preventing land depletion, and preventing the 'uncontrolled proliferation' of genetically modified food products.

Biotechnology can be defined in several ways but for this report the Organisation for Economic Co-operation and Development (OECD) definition is appropriate: 'Biotechnology is the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services'.

This means that biotechnology involves a diverse collection of technologies that manipulate molecular, cellular and genetic components and processes with a view to developing products and services for commercial and other purposes. The hallmarks of biotechnology are cellular and genetic techniques that manipulate cellular and sub-cellular building blocks for applications in various scientific fields and industries such as medicine, animal health, agriculture, marine life, bioenergy and environmental management. The development of biotechnology can be summarized in a rather simplified way as consisting of three phases:

- 1. The use of selected biological organisms to produce food and drink, for example, cheese, beer, wine;
- 2. The use of pure cell or tissue cultures to yield new products such as antibiotics, vitamins or enzymes; and

135/2009, 25 September 2009, on the Internet: http://www.realinstitutoelcano.org/wps/portal/rielcano_eng/Content?WCM_GLOBAL_CONTEX

Russian Federation (2009) 'Strategiia Natsional'noi Besopasnosti Rossiiskoi Federatsii do 2020 goda' [National Security Strategy of the Russian Federation up to 2020], Russian Security Council, 12 May 2009 (by Presidential Decree No. 537), on the Internet: http://www.scrf.gov.ru/documents/99.html (retrieved 10 December 2009); and Morales, Javier (2009) 'Russia's New National Security Strategy: Towards a "Medvedey Doctrine"?', ARI

T=/elcano/elcano_in/zonas_in/europe/ari135-2009 (retrieved 4 March 2010).

OECD definition of biotechnology, on the Internet:

http://www.oecd.org/about/0,3347,en_2649_37437_1_1_1_1_37437,00.html (retrieved 15 October 2009).

3. The application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

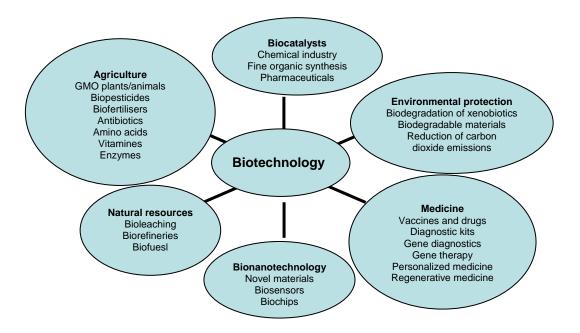


Figure 1. Schematic that shows different applications of biotechnology.

The modern biotechnology industry emerged in the 1970s, largely due to the development of new techniques like recombinant DNA techniques based on work by Stanley Cohen of Stanford University and Herbert Boyer of the University of California, San Francisco. Recombinant DNA enables the construction and production of proteins such as human insulin and other therapies in cultured cells under controlled manufacturing conditions. In 1982, recombinant human insulin became the first biotech therapy to earn U.S. FDA (Food and Drug Administration) approval. The product was developed by Genentech and Eli Lilly and Co. In 2009 there were more than 400 biotech drug products and vaccines currently in clinical trials, targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis.

Biotechnology has also made it possible to develop hundreds of new medical diagnostic tests that enable the detection of different medical conditions or diseases early enough for them to be successfully treated. DNA fingerprinting

has dramatically improved criminal investigation and forensic medicine. In agriculture, biotechnology has increased yields, reduced pesticide use and improved soil and water quality. In addition it has provided healthier foods for consumers. One growing sector is environmental biotechnology which makes it possible to clean up hazardous waste or degrade organic waste more efficiently. Industrial biotechnology shows promise for applications leading to more efficient and cleaner processes that produce less waste, and need less energy and water.

Table 1. Important Recombinant Therapeutic Proteins on the World Market¹⁰

Human insulin

Human somatropin (growth Hormone)

Interferon a

Erythropoietin

C-CSF Colony Stimulating Factor

Blood factor VIII

Interferon B

Glucocerebrosidase

Follicle-stimulating hormone (FSH)

Blood factor VII-α

Where the development of the pharmaceuticals industry is concerned, it should be remembered that for one new drug to reach the market requires very large investments in R&D as well as resources. Usually it takes 10–15 years to develop one new drug and it will cost around \$80–125 million. Only very few R&D attempts to find new drugs are successful. The biopharmaceuticals market is the fastest-growing sector of pharmaceuticals, even if it is still 2009 a small part of this sector. In the biopharmaceuticals area, recombinant insulin, other protein hormones, cytokines, colony stimulating factors and recombinant vaccines are fast growing areas. Some examples of important recombinant therapeutic proteins on the world market are given in Table 1. This is also the case for therapeutic monoclonal antibodies. A number of serious diseases are being targeted by research and development, such as diabetes, blood disorders, multiple sclerosis, different types of cancer, arthritis, ophthalmic disorders, and some infectious diseases like hepatitis and AIDS.

Bairamashvili, Dmitrij I. and Mikhail L. Rabinovich (2007) 'Russia through the Prism of the World Biopharmaceutical Market', *Journal of Biotechnology*, Vol. 2, Table 1, p. 802.

This study relies on a variety of sources, both Western and Russian, such as scientific review articles on Russian biotechnology and pharmaceutical progress, academic books on the historical developments in Russian biotechnology, official documents on plans and programmes, official statements by government, news media articles online, specialized news sources on Russian biotechnology (RusBiotech, EurasiaBio, Cbio.ru, Russian Biofuels Association), Russian company and institute websites, and business information, including market analysis. There has been no attempt to evaluate experimental R&D; instead the report focuses on material dealing with the industrial applications of biotechnology and analysis of how successful Russian companies are in this area.

2 Background and Historical Development

Russia has a fairly long history of research and development in the biological sciences which goes back to the time of Tsar Alexander II. Tsar Peter the Great initiated the establishment of the Academy of Sciences which met for the first time in 1725. The Imperial Academy of Sciences aim was to become the leading scientific institution in the country, which also suited the tsar as he distrusted the politicized university professors. It became much more influential than its European counterparts. The Academy met the Bolshevik Revolution with less open resistance than the universities and managed to survive and become even more influential under Soviet rule. 13

Before the 1917 revolution, although Russian science in general could not compete with leading industrialized countries, in some areas – among them biology and chemistry – it had achieved international recognition, with Dmitri Mendeleev, Ilya Mechnikov and Ivan Pavlov as examples of this. ¹⁴ Research was badly affected by the successive upheavals and troubles. ¹⁵ During the Stalin era Lysenko managed to totally dominate the field of biology and genetics, due to Stalin's support, with his misconceptions of inherited acquired characteristics.

That is that environmental factors were more important than genetics for inheritance. Genetics was deemed a pseudo-science and "bourgeois"

Many opposed his ideas, which were not scientifically based, and this resulted in widespread prosecution of scientists. ¹⁶ In the Soviet era dialectical materialism became the official Soviet philosophy of science and Marxism had a strong influence on many scientists, including prominent scientists. ¹⁷ In the Stalin era dialectical materialism was used in order to terrorize scientists and any scientific theory could be referred to as 'bourgeois', indicating that the scientist had shown disloyalty that could result in imprisonment or the death sentence. ¹⁸ It has been estimated that of the total number of engineers in the later part of 1920s around 50 per cent were arrested. The percentage of scientists was probably somewhat

¹¹ Rabinovich, Mikhail (2007b) 'Biotech in Russia, History of Biotech in Russia', *Journal of Biotechnology*, Vol. 2, pp. 775-7.

Graham, Loren R. (1993) Science in Russia and the Soviet Union: A short history (Cambridge, Cambridge University Press), p. 19.

¹³ Ibid., pp. 81-82.

¹⁴ Ibid., p. 80.

¹⁵ Rabinovich (2007b) 'Biotech in Russia', pp. 775-7.

¹⁶ Graham (1993) Science in Russia, pp. 121-6.

¹⁷ Graham, Loren R. (1998) What Have We Learned about Science and Technology from the Russian Experience? (Stanford, CA, Stanford University Press) p. 80.

¹⁸ Birstein, Vadim J. (2001) *The Perversion of Knowledge: The True Story of Soviet Science* (Cambridge, MA, Westview Press).

lower but the scientific community was not spared from the purges and prosecutions. 19

Lysenkoism is the most extreme example of the difficulties scientists faced during this period. One of several scientists who criticized Lysenko's ideas was a leading plant geneticist, Nikolai Vavilov, who was later arrested and died in a prison camp. He carried out expeditions to 64 countries and established the world's largest seed collection with 150 000 items. Scientists close to Vavilov were executed as enemies of the state. Lysenko's ideas came at a time when Soviet agriculture was in desperate need of improvement, as productivity was not increasing, and here Lysenko's ideas promised rapid progress. Lysenko denied the role of the gene and rejected Darwinism and Mendelian genetics in favour of a kind of neo-Lamarckism, whereby acquired traits could become hereditary. This view paralysed Soviet biology for decades. The Communist Party and Stalin supported Lysenko's views. Lysenkoism lasted from 1948 to around 1965 but was overtaken by the rapid developments in genetics and the improved agricultural practices in the West. The Soviet Union had lost many talented scientists and was far behind the West in the field of genetics.

At the beginning of the 1970s, a well-known molecular biologist, Yurii A. Ovchinnikov, (Vice-President of the Academy of Sciences), convinced the military leadership of the need to make significant investment in the development of biotechnology and to use the recent scientific advances for weapons purposes. Leonid Brezhnev, then general secretary of the Communist Party, decided to launch a major effort in 'biotechnology and genetic engineering' code-named Enzyme and to establish 1973 a new secret organization named Biopreparat. This organization was to consist of numerous research and production facilities, some of them specifically focusing on molecular biology and genetics for the military.²⁵ Substantial funding in foreign currency annually was secured for purchasing equipment and literature abroad

¹⁹ Graham (1998) What Have We Learned?, p. 55.

²⁰ Pringle, Peter (2008) The Murder of Nikolai Vavilov: The story of Stalin's persecution of one great scientist of the twentieth century (Simon and Schuster).

²¹ Graham (1993) *Science in Russia*, pp. 121-126.

²² After Jean-Baptiste Lamarck (1744–1819) French naturalist, early proponent of evolution and of the concept that it obeyed natural laws.

²³ Alibek, Ken with Stephen Handelman (1999) Biohazard, *The Chilling True Story of the Largest Covert Biological Weapons Program in the World – Told by the man who ran it* (London, Hutchinson).

²⁴ Graham (1998) What Have We Learned? pp. 22-3.

²⁵ Alibek with Handelman (1999) *Biohazard*, pp. 39-41; and Domaradskij, Igor V. and Wendy Orent (2003) *Biowarrior: Inside the Soviet/Russian biological war machine* (Amherst, NY, Prometheus Press), p. 143.

for the development of biological weapons. ²⁶ The programme included facilities within a number of ministries: the Ministry of Defence, Main Directorate Biopreparat, Ministry of Agriculture, Ministry of Chemical Industry, Ministry of Health, USSR (Union of Soviet Socialist Republics) Academy of Sciences, Committee on State Security (KGB) and Ministry of Internal Affairs. A total of 20–50 facilities were part of the programme and around 65 000 personnel, with 40 000 in Biopreparat, 15 000 in the Ministry of Defence and an additional 10 000 in the Ministry of Agriculture's facilities. ²⁷ Institutes of the Ministry of Health were also involved with the system of six anti-plague institutes with numerous epidemiological stations. ²⁸ The Biopreparat organization provided a scientific and production base consisting initially of at least six scientific production organizations: Biomash, Biosyntez, Enzym, FarmPribor, Progress and Vector. ²⁹ There was a perception that the U.S. had come much further than the Soviet Union in developing efficient biological weapons.

It was not until 1992 that Russia admitted that the work being carried out did not meet the requirements of and violated the international Biological and Toxin Weapons Convention (BTWC)³⁰ and that there was a delay in the implementation of this convention. Within the framework of the BTWC reporting on confidence-building measures to the United Nations, Russia admitted to having had an offensive programme. The joint statement of the trilateral process between the U.S., the UK and Russia included statements to the effect that offensive research would be terminated, lines for production of

²⁶ Domaradskij and Orent (2003) *Biowarrior*, p.155; and Rimmington, Anthony (1995) 'On the Eastern Front: Legacy of biotechnology visionary lives on', *Microbiology Europe*, Vol. 3, No. 3, pp. 14-15

pp. 14-15.

Alibek with Handelman (1999) *Biohazard*; Adams, James (1994) 'The Weapons of Special Designation', chapter 20 in *The New Spies – Exploring the frontiers of espionage* (Hutchinson, London), pp. 270-283; Smithson, Amy E. (1999) *Toxic Archipelago: Preventing proliferation from the former Soviet chemical and biological weapons complexes*, Report No. 32, Henry L. Stimson Center, December, p. 9; Domaradskij and Orent (2003) *Biowarrior*; Rimmington, Anthony (2000) 'Invisible Weapons of Mass Destruction: The Soviet Union's BW programme and its implications for contemporary arms control', *Journal of Slavic Military Studies*, Vol. 13, No. 3 (September), pp. 1-46; Shohan, D. and Z. Wolfson (2004) 'The Russian Biological Weapons Program: Vanished or disappeared?', *Critical Reviews in Microbiology*, Vol. 30, pp. 241-61; Hart, John (2006) 'The Soviet Biological Weapons Program', Chapter 6, in M. Wheelis, L. Rozsa and M. Dando (eds), *Deadly Cultures* (London, Harvard University Press,), pp. 132-56; and Roffey, Roger, Wilhelm Unge, Jenny Clevström and Kristina Westerdahl (2003) Support to Threat Reduction of the Russian Biological Weapons Legacy – Conversion, Biodefence and the Role of Biopreparat, Report, FOI-R--0841--SE (Umeå, FOI).

Zilinskas, Raymond A. (2006) 'The Anti-Plague System and the Soviet Biological Warfare Program', *Critical Reviews in Microbiology*, Vol. 32, pp. 47-64.
 Hart. John (2006) 'The Soviet Biological Weapons Program', p. 140.

³⁰ BTWC (1972) Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, on the Internet: http://www.unog.ch/80256EDD006B8954/(httpAssets)/C4048678A93B6934C1257188004848D <a href="http://www.unog.ch/80256EDD006B8954/(httpAssets)/c4048678A97848D006B8954/(httpAssets)/

biological agents would be dismantled and biological weapons testing sites would be closed, as well as dissolving the Ministry of Defence department responsible for the offensive programme.³¹ At the same time it should be borne in mind that it was not at all unusual to perform research for the military, a reflection of 'the wish of the military to retain maximum influence in all aspects of Soviet life'.³² Thus the biotech revolution in the Soviet Union came to be closely linked to the military R&D programme.

A series of new institutes were established for developing different aspects of microbiology and biotechnology, but without disclosing their real purpose as part of the military effort to develop biological weapons. Two of these built in the early 1970s, the Institute for Applied Microbiology in Obolensk south of Moscow and the Institute of Virology Vector in Koltsovo, conducted research of high international standard in terms of studies of certain dangerous pathogens. Some of this research was more advanced than that done in the West during the 1980s.³³ Most of this research was and still is classified. The research publications of the Institute for Applied Microbiology were analysed from 1982 to 2003.³⁴ It was found that the institute carried out high-quality research in molecular biology and was in the forefront during the 1980s – in specific areas, one or two decades ahead of the West. Scientists there had discovered the plasmids of the plague pathogen long before Western researchers.³⁵ A detailed analysis of Soviet and Russian research on toxins and bioregulators led to the assessment that the know-how was of relatively high international class.³⁶

For a long time, a group of institutes called the anti-plague institutes have collected significant knowledge on dangerous pathogens such as those causing plague, anthrax, brucellosis, tularaemia, cholera or Crimean-Congo haemorrhagic fever. The anti-plague system in the Soviet Union consisted of four

³¹ President Boris Yeltsin (1992) 'Decree of the President of the Russian Federation, Edict no 390, B. Yeltsin', Moscow, 11 April; 'Joint U.S./UK/Russian Statement on Biological Weapons', 14 September 1992, on the Internet: http://www.fas.org/nuke/control/bwc/text/joint.htm (retrieved 10 December 2009); and Knoph, Jan T. and Kristina S. Westerdahl (2006) 'Re-Evaluating Russia's Biological Weapons Policy, as Reflected in Criminal Code and Official Admissions: Insubordination leading to a president's subordination', *Critical Reviews in Microbiology*, Vol. 32, pp. 1-13.

³² Adams, James (1994) 'The Weapons of Special Designation', pp. 270-83.

³³ Domaradskij and Orent (2003) Biowarrior; Domaradskij, Igor V. and Wendy Orent (2006) 'Achievements of the Soviet Biological Weapons Programme and Implications for the Future', Rev. Sci. Tech. Off. Int. Epiz., Vol. 25, No. 1, pp. 153-61; Häggström, Britta, Åke Forsberg and Lena Norlander (2004) Conversion of a Former Biological Weapons Establishment, Report FOI-R--1316--SE (Umeå, FOI); and Clevström, Jenny, Lena Norlander and Wilhelm Unge (2000) Rysk toxin- och bioregulatorkompetens [Competence in Toxin and Bio Regulation in Russia], Report FOA-R--01703-170--SE (Umeå, FOA).

³⁴ Häggström, Forsberg and Norlander (2004) Conversion of a Former Biological Weapons Establishment.

³⁵ Domaradskij and Orent (2003) *Biowarrior*, p. 116.

³⁶ Clevström, Norlander and Unge (2000) Rysk toxin- och bioregulatorkompetens.

parts. The first part controlled by the Second Directorate of the Soviet Union Ministry of Health had six anti-plague institutes with around 100 subordinate regional, field, and seasonal anti-plague stations and laboratories to cover the country. A second system, controlled by the Third Directorate of the Soviet Union Ministry of Health, was made up of institutes that monitored the natural situation concerning endemic plague surrounding uranium mines. A third system, controlled by the Ministry for Railways, was the so-called railroad anti-plague stations along railway lines. A fourth system was anti-epidemic stations, controlled by the Ministry of Defence, which reported to the Central Military Medical Directorate.³⁷ It was only around 1950–1960 that the anti-plague institutes became engaged in the Soviet biological weapons programme (codenamed Ferment) and the programme for biological defence (code-named Problem 5).

One institute, the Volgograd Anti-plague Institute, was the only one that was entirely engaged in the biological weapons programme. For the rest this was only one part of their activities.³⁸ The directions for the system's biological weapons or biological defence work were given by the Civil Defence Headquarters of the Ministry of Defence channelled through the Second Directorate of the Ministry of Health or funding through the organization of Biopreparat and Glavmikrobioprom. When the Soviet Union collapsed the anti-plague system consisted of 10 000 personnel. The system was subordinated to the Ministry of Health's Main Sanitary Epidemiological Directorate (MSED) and the Department of Especially Dangerous Infectious Diseases which supervised the work until 1971 when this was taken over by the Directorate of Quarantine Infections (DQI).³⁹

The anti-plague institutes had an important role for disease surveillance, developing methods and vaccines as well as training of civilian and military personnel. The system covered what is today Russia and eleven other former Soviet republics. The first anti-plague institutes were established at the end of the 1800s and the beginning of the 1900s, such as the Institute of Experimental Medicine, established 1890 in St Petersburg, and a laboratory established in 1897 at a fortress on an island in the Gulf of Finland, Fort Alexander I; it was named the Special Laboratory of the Imperial Institute of Experimental Medicine for the Production of Anti-plague Preparations (closed in 1917). In 1918 the Anti-plague Institute in Saratov was opened (later named the State Regional Institute of

Ouagrham-Gormley, Sonia B., Alexander Melikishvili and Raymond A. Zilinskas (2006) 'The Soviet Anti-Plague System: An introduction', *Current Reviews in Microbiology*, Vol. 32, pp. 15-

Ouagrham-Gormley, Melikishvili and Zilinskas (2006) 'The Soviet Anti-Plague System', pp. 15-17.

Ouagrham-Gormley, Sonia B. (2006) 'Growth of the Anti-plague System during the Soviet Period', *Current Reviews in Microbiology*, Vol. 32, pp. 33-46.

Microbiology and Epidemiology, Mikrob). The background to the establishment of anti-plague institutes was Russia's long history of outbreaks of plague (*Yersinia pestis*). ⁴⁰ Between 1920 and 1950 the number of institutes in the antiplague system increased to 87. In the 1960s and 1970s the system consisted of 14 000 personnel, including 7000 scientists, and the institute in Saratov became the leading institute. ⁴¹ In 1938 the Soviet Government decided that diseases like plague and cholera had been eradicated. All information on outbreaks was therefore considered a state secret after this date. ⁴²

Great efforts were made to acquire Western knowledge in the biotechnology area and major new investments were made in biotechnology and genetic engineering, especially in the military for weapons development. This engaged the Soviet intelligence agencies in collecting scientific and defence-related information in the biological area from the West. This was a large operation during the Soviet period and was directed by Department 12 of Directorate S (Special operations) of the Foreign Intelligence Service (the First Main Directorate of the KGB). The aim was to collect technical information that could help in the development of Soviet biological weapons. A special focus was on work in genetic engineering and on dangerous human and animal pathogens and toxins. Department 12 was interested in monitoring activities in specific laboratories. institutes, centres and private companies involved in biotechnology and secret R&D programmes dealing with protection against biological weapons.⁴⁴ This continued even though the Soviet Union signed the BTWC, the total ban on the acquisition, development and production of biological and toxin weapons from 1972. Alexander Kouzminov implies that this type of intelligence gathering did not end after the collapse of the Soviet Union but rather increased and became more directed towards industrial espionage in the area of biotechnology.

During the Cold War there was very rapid development in the biological sciences in the Soviet Union, based on the efforts by the military–industrial complex to keep up with the pace of developments in the West. During this period a large number of facilities were built for advanced research but also for large-scale industrial production such as antibiotics, biological pesticides, enzymes (around 10 000 tonnes per year), vitamins and animal feed protein (single cell protein)

⁴⁰ Melikishvili, Alexander (2006) 'Genesis of the Anti-Plague System: The tsarist period', *Current Reviews in Microbiology*, Vol. 32, pp. 19-31.

⁴¹ Ouagrham-Gormley (2006) 'Growth of the Anti-plague System', pp. 33-46.

⁴² Ouagrham-Gormley (2006) 'Growth of the Anti-plague System', pp. 33-46; and Ouagrham-Gormley, Sonia B. (2006) 'Plagued by Errors: New approach needed to tackle proliferation threats from anti-plague system', *Arms Control Today*, March.

⁴³ The First Chief Directorate, the Foreign Intelligence Service of the KGB, since 1991 renamed the Russian Foreign Intelligence Service, FIS, now known as the SVR.

⁴⁴ Kouzminov, Alexander (2005) Biological Espionage: Special operations of the Soviet and Russian foreign intelligence services in the West (London, Greenhill Books).

⁴⁵ Ibid

which was based on relatively simple production technologies. The Soviet Union had the world's largest programme for the production of single cell protein – 1.5 million tonnes annually – and for animal feed and lysine – 35 000 tonnes annually. The Soviet Union produced enough vaccines for its own use – around 300 tonnes of each antibiotic and a total of 3000 tonnes per year of active pharmaceutical ingredients – in large plants in Kurgan, Penza, Kranoyarsk and Saransk. Biochemical plants in Kurgan, Sverdlovsk and Novisibirsk produced vitamin B12 and β -carotene. Enzymes for medical needs were produced in Berdsk. 47

Also during this period a very extensive and sophisticated biological weapons programme was further extended and given priority, peaking around 1980. This became the key driver for national developments in biotechnology, including knowledge on dangerous pathogens in the Soviet Union. For strategic reasons, the Soviet Union built up biotech production capabilities which came to account for 5 per cent of the world market value in biotechnology products. At this time 80 per cent of the equipment for the biotechnology industry was domestically produced. During this period the Soviet Union actively collected information through the intelligence services on the latest advances in biotechnology, including defence applications in the West, in an attempt to improve its own research performance and applications in biotechnology.

A detailed review of the Russian vaccine industry revealed that all its products manufactured during the 1990s were based on traditional microbiology and virology methods. ⁴⁹ A Ministry of Health official noted in 1992 that Russia was still five to eleven years behind the West in the development of vaccines. ⁵⁰ Work had been carried out on one genetically engineered vaccine without reaching the production stage. ⁵¹ Recombinant human growth hormone had been recognized as a potential biotech product as early as in the first half of the 1980s. In April 1986, scientists reported small-scale production of insulin and growth hormone and an experimental line for interferon production, but it was not until a decade later that these were industrially produced. ⁵² Recombinant α -2 interferon (Reaferon) for

⁴⁶ Greenshields, Rod, Anthony Rimmington and Harry Rothman (1990) 'Perestroika and Soviet Biotechnology', Technology Analysis and Strategic Management, Vol. 2, No. 1, pp. 63-76.

⁴⁷ Bairamashvili, Dmitrij I. and Mikhail L. Rabinovich (2007) 'Russia through the Prism of the World Biopharmaceutical Market', *Journal of Biotechnology*, Vol. 2', p. 803; and Rabinovich (2007b) 'Biotech in Russia, History of Biotech', pp. 775-7.

⁴⁸ Bairamashvili and Rabinovich (2007) 'Russia through the Prism', p. 804.

⁴⁹ Westerdahl, Kristina S. (2001) Building and Measuring Confidence: The Biological and Toxin Weapons Convention and vaccine production in Russia, Report FOI-R--0189--SE (Umeå, FOI).

Denisov, I. N. (1991) 'Infectious Disease and Objectives of Medical Science and Health Care in the Prevention of such Diseases', *Zhurnal mikrobiologii*, *epidemiologii*, *i immunobiologii*, No. 11, pp. 2-7; English translation in JPRS-ULS-93-002 (1993), pp. 12-8.

⁵² Rimmington, Anthony (1987a) 'The Impact of Biotechnology upon Agriculture in the USSR; part I', *International Industrial Biotechnology*, Article 100:7:6/7, pp. 334-8; and Rimmington,

the treatment of cancer and hepatitis was produced by an institute located in present-day Lithuania.⁵³ It took until 1995 for a genetically engineered product to be approved by the Russian regulatory authorities – the interleukin Ronkoleukin for cancer treatment.⁵⁴ It is produced by OOO Biotekh, a spin-off company from the Biological Scientific Research Institute, St Petersburg.⁵⁵

The All-Union Institute of Enzymology, situated in Lithuania, started selling molecular biology products as early as 1983 and was the producer of the first product of this kind to pass clinical trials for use in humans. 56 In 1994, 100 of the personnel at the Institute of Biotechnology, formerly the All-Union Institute of Enzymology, left to form the company Fermentas. This is now a thriving company and sales in 2006 were \$18.4 million, consisting mostly of enzymes but also other tools for molecular biology. The company has offices or distributors in 70 countries.⁵⁷ According to a World Bank report, Fermentas was 'one of the largest enzyme producers in the world' with about 5–6 per cent of the global market for molecular biology enzymes.⁵⁸ At the time Fermentas was formed another group of 125 scientists from the same institute established the company Biofa, later called Biotechna and now UAB Sicor Biotech, ⁵⁹ with the intention of producing human growth hormone⁶⁰ and interferon-α-2b (brand name Realdiron, 2000) Biotechna opened a plant meeting international quality standards in 2000, built by a Swedish company. It represented an investment of \$200 million. These examples show that under the right circumstances successful biotechnology initiatives were possible and that the know-how was good.

Anthony (1987b), 'The Impact of Biotechnology upon Agriculture in the USSR; part II', *International Industrial Biotechnology*, Article 105:7:8/9, pp. 351-3.

53 Rimmington (1995) 'On the Eastern Front', pp. 14-5.

⁵⁹ Institute of Biotechnology homepage, on the Internet: http://www.ibt.lt/english/about.htm (retrieved 12 May 2007).

National Science Foundation (1997) Report No. 85, Science in Lithuania, on the Internet: http://www.nsf.gov/pubs/stis1997/int971/int971.txt (retrieved 8 May 2007).

Farmatsevticheskii Vestnik (1999) 'Lechenie rasseiannogo skleroza mozhet boitis' v 10 raz deshevlee' [Treatment of Multiple Sclerosis can be 10 times Cheaper], No. 25 (11 September), on the Internet: http://www.pharmvestnik.ru/cgi-bin/statya.pl?sid=1679 (retrieved 7 May 2005).

⁵⁵ OOO Biotekh homepage, on the Internet: http://www.biotech.spb.ru/ (retrieved 7 May 2005).

⁵⁶ Institute of Biotechnology homepage, on the Internet: http://www.ibt.lt/english/about.htm (retrieved 12 May 2007).

⁵⁷ Fermentas' homepage, on the Internet: http://www.fermentas.com/ (retrieved 7 May 2007); and DNA Enzymes Project, research group presentation for Fermentas (2004), on the Internet: https://genesilico.pl/DNAenzymes/research_groups/fermentas (retrieved 9 May 2007).

⁵⁸ Handbook on Urban Economic Base Analysis, Appendix A: Vilnius Market Profile: Foreign investment and export markets (1997), on the Internet: http://www1.worldbank.org/wbiep/decentralization/FDIReadings/econbase%20b.htm (retrieved 7

⁶¹ Öberg, Johan (2000) 'I dag invigs en ny bioteknikfabrik i Vilnius' [New biotech factory opens today in Vilnius] Dagens Industri, 20 October; on the Internet:

http://www.sicor.lt/en/disp.php/en_publications/en_publications_aus/en_publications_aus_2

(retrieved 8 May 2007).

In the Soviet era the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry had the technology to produce genetically engineered insulin, but the disintegration of the USSR prevented transfer into industrial production. The first production of recombinant human insulin was made using a recombinant strain of E. coli, by the All-Union Institute of Antibiotics in Moscow in cooperation with Genbiotech GmbH in Heidelberg in 1987–1989. 62 In 1996, an efficient strain producing human pre-proinsulin was constructed by the Institute for Applied Microbiology in Obolensk under RAO Biopreparat which was used for the scaling up of production which started in 2003.⁶³ A specific facility, OAO National Biotechnology, was created for full-scale production with financial support from Gazprom.⁶⁴ Production was carried out in 3000-litre fermenters and the annual production in the pilot plant 2006 was 10 kg API (active pharmaceutical ingredient) recombinant human insulin.65 In March 2007, a fifth of the recombinant insulins required in the country were being produced inside Russia.66

By 1990 there were several thousand scientific research institutes in Russia, most of them under industrial ministries.⁶⁷ At this time there were around 600 institutes under the Academy of Sciences (for examples of research institutes, see Appendix 3).⁶⁸ Overall, this structure was a legacy from the Soviet Union. The Soviet research system was highly centralized and the Academy of Sciences played an important role. Being a member of the Academy of Sciences, an akademik, and even being a corresponding member carried high prestige in the Soviet Union and was connected with many benefits and privileges.⁶⁹ Funding was done through block funding of institutes, giving directors a great deal of power. It was not done by projects, which is why the system emphasized quantity before quality. ⁷⁰ Even if Soviet science achieved some impressive results it

Rimmington (1987a) 'The Impact of Biotechnology, part I', pp. 334-8; and Rimmington (1987b), 'The Impact of Biotechnology, part II', pp. 351-3.

⁶³ This was made possible due to a decree on measures to support diabetes by President Yeltsin (the Federal Targeted Program Diabetes) and financial support in 2000 from Moscow Mayor Luzhkov (due to personal contacts).

⁶⁴ NAS (2006) 'Committee on Future Contribution of the Biosciences to Public Health, Agriculture, Basic Research, Counterterrorism, and Nonproliferation Activities in Russia', in Biological Science and Biotechnology in Russia (Washington, DC, National Academies Press).

⁶⁵ Bairamashvili and Rabinovich (2007) 'Russia through the Prism', pp. 801-17.

⁶⁶ Advis.ru (2007), 'Putin: Russia has to produce its own medicines', 6 March, on the Internet: http://www.advis.ru/cgi-bin/printnew.pl?786B7EAD-D01B-8142-9C66-8FB48231F376 (retrieved 7 March 2007).

⁶⁷ For a complete recent list of universities etc. in the Russian Federation, see on the Internet: http://www.university-directory.eu/Russian-Federation-(Russia)/Russian-Federation-(Russia).html (retrieved 10 Dcember 2008). Graham (1993) Science in Russia, p. 174.

⁶⁹ Graham (1998) What Have we Learned? p. 83.

⁷⁰ Ibid., p. 84.

performed poorly considering the number of scientists involved and level of funding.⁷¹

This also meant that the government could easily divert significant resources for high-priority areas such as development of nuclear or biological weapons. Research was organized under the State Planning Commission (GOSPLAN) of the Council of Ministers and above it the Communist Party acting through the Central Committee or the Politburo. Under this there was the academy system of scientific research institutes, universities and technical institutes and the ministerial research establishments such as industrial research institutes. In 1965 the State Committee for Science and Technology was established for the coordination of mainly industrial research and the Academy of Sciences was given the responsibility for coordinating fundamental research. This coincided with the transfer of around half of the research institutes under the Academy of Sciences to industrial ministries. However, the State Committee for Science and Technology did not have any laboratories of its own as the Academy did.

Several attempts were made during 1970s and 1980s to reorganize research and development, including production, into 'association', 'technological centres', 'complexes' and so-called science production associations (NPOs), of which there were about 3000. Many of the NPOs, usually under the control of production ministries, were not able to engage the best fundamental research scientists. At the end of the 1980s private initiatives were established as well as organizations called Interbranch Scientific-Technical Complexes (MNTKs) which engaged both production and institutes under the Academy of Sciences. One was devoted to biotechnology. The MNTK organizations soon lost their importance as a result of criticism and privatization. Furthermore, in the late 1980s research institutes were allowed to initiate joint ventures with Western entities.

After the fall of the Soviet Union and the coup in August 1991, the USSR Academy of Sciences was taken over by the new Russian Academy of Sciences (RAS). In spite of a number of changes and minor modifications, the role of the RAS was similar to that of its predecessor.⁷² At this time the State Committee on Science and Technology of the USSR (GKNT) was abolished and its functions were transferred to the Ministry of Science, Higher Education and Technological Policy of Russia. Many of the scientific research institutes were experiencing severe financial difficulties and Russian science was in deep crisis in 1992. Many scientists emigrated abroad for shorter or longer stays.⁷³ There was a fear in the West that scientists with specific, sensitive know-how might sell their knowledge

⁷¹ Gerber, Theodore P. and Deborah Y. Ball (2008) Scientists in a Changed Institutional Environment: Subjective adaptation and social responsibility norms in Russia, 27 June, Lawrence Livermore Lational Laboratory, Report LLNL-JRNL-405009.

⁷² Graham (1998) *What Have We Learned?* pp. 90-3.

to countries of concern and a series of financial support programmes were initiated.

Scientists and engineers from the military–industrial complex were the part of the scientific community that experienced the deepest financial cuts after the fall of the Soviet Union. At that time there were around 800 000 engineers and 80 per cent of them belonged to the military–industrial complex. It is difficult to estimate the number of scientists that left Russia after the fall of the Soviet Union. The U.S. State Department estimated that during the four years 1990–1993 around 10 000 scientists and engineers left the country, and the OECD estimate was 30 000 scientists and engineers (the latter estimate includes undergraduates).

In 1991 the official figure for the number of scientists was 1 520 000, divided into three categories belonging to the university system (600 000 researchers with 7 per cent of the R&D budget), the industrial and defence ministry system (125 000 researchers with 6.5 per cent of the R&D budget) and the Academy of Science system (800 000 researchers with 87 per cent of the R&D budget). The Soviet Union had the world's largest scientific establishment and by any comparison the output was meagre.

During the Yeltsin period (1991–1999) extensive privatization of Russian industry was carried out, including in the biotechnology industry. This also resulted in dramatic reductions in the state financing of national R&D.⁷⁸ From 1990 to 1994 the number of scientists declined by 50 per cent.⁷⁹ It was estimated that Russia had lost around 200 000 scientists between 1992 and 2007.⁸⁰ The federal funding for scientific research declined from 1991 to 1994 by about 75 per cent, a level on which it had remained. At the end of the 1980s, 97 per cent of science was funded through the federal budget.⁸¹ Estimates indicated that in total around 40 per cent of scientists had left research or the country over the decade

⁷⁴ Graham (1998) What Have We Learned? pp. 48-9.

⁷⁵ Science (1994) 'Storm Clouds Over Russian Science', *Science*, Vol. 264, No. 27 (May), pp. 1259-82.

⁷⁶ Graham (1998) What Have we Learned? p. 62.

⁷⁷ Ibid., Table p. 157.

Nezavisimaia gazeta, 2 February; and Vaganov, A. (2001) 'Brain Drain: The loss of intellectual capital', in Viad Genin (ed.) The Anatomy of Russian Defence Conversion (Walnut Creek, CA, Vega Press), p. 387; Chodarenk, M. (2001) 'Voiennaia reforma' [Military reform is going round in circles], Nezavisimaia gazeta, 2 February; and Vaganov, A. (2001) 'Vishneovyij sad...' [The Cherry Orchard of Russian Science], Nezavisimaia gazeta, 16 February.

⁷⁹ Ushkalov, I. G. and I. A. Malakha (1999) 'Utechka Umov: Prichiny, Masshtaby, Posledstvii' [Brain Drain: Reasons, scale, consequences], Editorial, URSS, Moscow, p. 51: and Gokhberg, L. and L. Mindeli (1999) 'Nauka Rossii v Tsifrakh' [Russian Science in Numbers], Tsentr Issledovannii i Statiski Nauk, Moscow, p. 28.

⁸⁰ Bairamashvili and Rabinovich (2007) 'Russia through the Prism', p. 812.

⁸¹ Ball, Deborah Y. and Theodore P. Gerber (2005) 'Russian Scientists and Rogue States', International Security, Vol. 29, No. 4, pp. 50-77.

of the 1990s. The numbers could be as high as 60-70 per cent of the scientific staff leaving research for other areas or going abroad. 82 It was the so-called branch institutes and design bureaux responsible for applied R&D that had formed the bulk of Soviet R&D that were the hardest hit by the collapse of the Soviet Union. The design bureaux became separated from R&D institutes due to the dissolution of the scientific and industrial complexes. The situation for research equipment was very bad during the 1990s with a rate of renewal of less than 2 per cent. This together with the low salaries for scientists was often given as a reason for qualified scientists to go abroad. The number of scientists leaving R&D inside the country is far greater than those that went abroad. It is also fairly common that scientists had more than one jobb and only spent part of their time in the R&D institutes. This was allowed as the budget for institutes was according to the number of personnel at institutes not taking into account the time they spent on research.⁸³ The problems were similar for both civilian and military research, resulting in an ageing scientific community and outdated laboratory equipment.⁸⁴ There is talk of a lost generation of researchers, especially in the biological field. All this has led to a distorted age structure at research institutes and in the Medical Academy. In 2003 the proportion of researchers over 45 years was 60 per cent while only 15 per cent of the researchers were between 30 and 45 years of age. 85 A direct result was that the biotechnological production decreased by a factor of 4-10 times. 86 The state could not finance the large amount of research and the large staff. There were further cuts in the funds for R&D and in 2009 these cuts concerning basic research were estimated to be around 30 per cent, which was significant.

The Russian leadership discussed drastically reducing the number of institutes and number of researchers, but many in the management of their institutes felt a responsibility for their staff and priority was given to paying salaries instead of investing in modern laboratory equipment. In 2005 the total number of R&D organizations was down to 3655, employing 813 207 persons, of whom 48 per cent were scientists. In 2009 The Russian Academy of Science was the largest research organization with 451 research institutes. The Russian Academy of Medical Sciences had 66 institutes and the Russian Academy of Agriculture 297

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⁸² Shulunov (2001) 'Brain Drain: The loss', p. 387; Chodarenk (2001) 'Voiennaia reforma'; and Vaganov (2001) 'Visheovyi sad'.

⁸³ Yegerov, Igor (2009) 'Post-Soviet Science: Difficulties in the transformation of the R&D systems in Russia and Ukraine', *Research Policy*, Vol. 38, pp. 600-9.

⁸⁴ Leijonhielm, Jan et al. (2002) Den ryska militärtekniska resursbasen, rysk forskning, kritiska teknologier och vapensystem [The Russian Military-Technical Resource Base, Russian Research, Critical Technologies and Weapons Systems], Report FOI R--0618--SE (Stockholm, FOI), October. p. 24.

⁸⁵ NAS (2006) 'The Human Resource Base', in *Biological Science and Biotechnology in Russia*, p. 61

⁸⁶ Rabinovich, Mikhail (2007a) 'Editorial: Biotech in Russia – Phoenix reborn from the ashes', Journal of Biotechnology, Vol. 2, p. 771.

(for examples of institutes in the biological area see Appendix 3). Some cities had been nominated as 'science towns', such as Koltsovo and Puchshino in the biotechnology area.⁸⁷

In 1993, the Russian state designated some of the leading institutes to become State Scientific Centres and greatly increased their resources. Examples of such institutes were the Institute for Virology, Vector in Koltsovo and the Institute for Applied Microbiology in Obolensk. However, the resources allocated were not as substantial as could be expected. 88 In 2005 it was stated that 58 organizations would retain their status as state scientific centres, including the institutes in Obolensk and Vector in Novosibirsk. 89

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⁸⁷ Ivanova, Natalia et al. (2007) INNO-Policy TrendChart – Policy Trends and Appraisal Report (Brussels, European Commission, DG Enterprise).

⁸⁸ NAS (2006) 'Pillar Two, Meeting Pathogen Research Challenges', in *Biological Science and Biotechnology in Russia, Controlling Diseases and Enhancing Security* (Washington, DC, National Research Council of the National Academies, NAS Press), p. 42.

⁸⁹ Russian BW Monitor (2005) 'Russia Preserves Status of Bioscience State Scientific Centres', Russian BW Monitor, on the Internet: http://www.russianbwmonitor.co.uk (retrieved 11 February 2005).

3 Defence Applications

The military drive to exploit advances in biotechnology and genetic engineering to develop improved biological weapons also created the base for the development of modern biotechnology in Russia. 90 Biotechnology has been the continued priority of the military with defence programmes focusing on critical chemical and biological technologies of a dual-use nature. 91

In 2006 the Military-Industrial Commission (MIC) of Russia, speaking on behalf of the Russian Government, published a White Paper on non-proliferation of weapons of mass destruction, including reference to biological weapons.⁹² According to the White Paper, Russia has consistently recommended that the Biological and Toxin Weapons Convention (BTWC) needs to be strengthened, especially in the light of the existence of covert foreign military biological weapons programmes, the fact that not all states are yet parties to the BTWC, and the risk that biological weapons will be used in 'internal conflicts'. Another concern is the potential for misuse of the rapid developments in biotechnology for terrorism or weapons purposes. One of the main concerns is that terrorists could get hold of biological agents and use them for bioterrorism. This makes security in the defence sector a priority. 93 There have been some indications that separatists in Chechnya could possess such agents. 94 The risk that advances in biotechnology could be used to produce new types of biological weapons has been described by Russia in a document on recent developments in science and technology presented at the 6th Review Conference within the framework of the Biological and Toxin Weapons Convention:

⁹⁰ Domaradskij, Igor V. and Wendy Orent (2006) 'Achievements of the Soviet Biological Weapons Programme and Implications for the Future', *Rev. Sci. Tech. Off. Int. Epiz.*, Vol. 25, No. 1, pp. 153-61.

⁹¹ Security Council of the Russian Federation, 'Osnovy politiki Rossiiskoi Federatsii v oblasti razvitia nauki i tekhnologii na period do 2010 i dal'neishuiu perspektivu' [Foundations for Russian Federation Policy for the Development of Science and Technology in the Period up till 2010 and Beyond'], on the Internet: http://www.scrf.gov.ru/Documents/Decree/2002/30-03.html (retrieved 15 October 2006).

ONS (2006) 'The Russian Federation and Nonproliferation of Weapons of Mass Destruction and Delivery systems: Threats, assessments, problems and solutions', June 2006, CNS translation of a Russian Government white paper on non-proliferation policy, James Martin Center for Nonproliferation Studies, on the Internet: http://cns.miis.edu/pubs/other/rusfed.htm (retrieved 15 October 2007); and Sokov, Nikolai (2006) 'CNS Analysis of the Russian Government's White Paper on WMD Nonproliferation' (The Russian Federation and the Situation with Nonproliferation of WMD and Means of Their Delivery: Threats, Assessments, Tasks, and Methods of Implementation) (Monterey Institute for International Affairs, CA) on the Internet: http://cns.miis.edu/pubs/week/060726.htm (retrieved 15 October 2007).

⁹³ RIA Novosti (2005b) 'Georgia's Authorities Doubt Possibility of Biological Weapons Development in Rankisi', *RIA Novosti*, 1 March 2005; and Moscow Times, 'FSB Says Terrorists are Trying to Secure WMD', *Moscow Times*, 22 August.

⁹⁴ RIA Novosti (2005a) 'North Caucasus Security Watch', RIA Novosti, 1 December.

- Risks that are highlighted are: increasing the virulence or antibiotic resistance
 of pathogenic microorganisms, changing the properties of agents so that they
 can more easily be dispersed by aerosol, and creating new or modified
 microorganisms that can infect people.
- Results from the Human Genome Project point to a scientific basis for the development of so-called genetic or ethnic weapons.
- Another risk is the development of nanotechnology, which means that small nano-particles, which can cross the human biological barriers, can be combined with toxic or other physiologically active substances and result in new weapon types.
- Prions are also identified as a risk in terms of new biological weapons.
- Physiologically active substances or bio-regulators could constitute a basis for constructing new biological weapons, including non-lethal ones.
- There is a risk of substances being directed against the human genetic material without causing disease. 95

This gives an idea of the types of biological threats the Russian biodefence programme will be aiming to protect against.

In 2007, a total ban on the export of biological or medical preparations was imposed in Russia in the light of the Federal Security Service (FSB) stressing the growing threat of bioterrorism and the fact that Western countries were developing genetically modified biological weapons. Another reason may have been that a Russian scientist from the Gamaleya Institute was arrested in 2006. He had carried a vaccine strain of *R. prowasekii* when leaving Russia to go to the institute he worked with in France. The FSB has since then conducted interrogations, claiming that the material was to be used for biological weapons. According to the FSB, the samples were analysed at a hitherto unknown military institute. He had social Development. It would severely disrupt biological research, which is often carried out in international cooperation, and could discourage foreign companies that want to conduct clinical trials in Russia for newly developed pharmaceuticals. Whether this ban was initiated in an attempt to strengthen Russia's own pharmaceuticals industry is unclear. However, the ban was lifted as

Schiemeier, Quirin (2007) 'Russian Scientists See Red over Clampdown', *Nature*, Vol. 449 (13 September), pp. 122-3.

⁹⁷ Kommersant (2007) 'Russia Warily Eyes Human Samples, in the Name of Fighting Bioterrorism, Export of Biological Materials Prohibited', *Kommersant*, 30 May.

⁹⁵ Russian Federation (2006) 'Scientific and Technological Developments Relevant to the Biological Weapons Convention, Submitted by the Russian Federation', Sixth Review Conference of the Biological and Toxin Weapons Convention. 20 November to 8 December. Geneva.

early as in June 2007 when the modified rules for exports were introduced.⁹⁸ This can be seen as a sign of continued suspicion from the Russian side of Western, not least the U.S., extensive biological defence research conducted in the area.

Russia initiated a major programme covering the years 1999–2005 to improve protection against bioterrorism, but this has not been followed by further openly declared initiatives. During Vladimir Putin's tenure as president, bioterrorism was described by the government as a reality that must be taken into account in planning. For measures against bioterrorism to be effective, they required a balanced and well coordinated approach at the federal, regional and local levels. A number of legal actions were proposed, including strengthening security at facilities, reducing the number of institutes working with the most dangerous types of pathogenic agents belonging to the highest risk groups (around 160 in the Russian Federation), providing these institutes with armed guards and introducing special entry systems.

A specific programme was adopted in 2008 for the period 2009–2013 with a budget of 28.7 billion roubles for biological and chemical security, including at plants, with 6.8 billion roubles for R&D, 16.9 billion roubles for investment and 4.9 billion roubles for other needs. This included the modernization and reequipment of 30 dangerous chemical and biological facilities, and twelve training centres would be established. Rapid methods for the diagnosis, identification or detection of dangerous pathogens, special measures to protect nine culture collections and decontamination methods were priorities in the biological area. Fifteen centres with modern equipment for rapid diagnosis of dangerous pathogens would be established under the Ministry of Agriculture (two), the Ministry of Defence (two), the Federal Service for Supervision in the field of human consumers and welfare (eight) and the Federal Medico-Biological

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⁹⁸ Kommersant (2007) 'Russia Warily Eyes'; and 'Russians Left in the Dark Despite Lifted Export Ban', *Industry Drivers*, 20 June.

⁹⁹ Russian Federation (1999) 'Resolution No. 737 Concerning the Focused Federal Programme for the Creation of Methods and Means of Defending the Population and Environment Against Hazardous and Extremely Hazardous Pathogens in Natural and Manmade Emergency Situations from 1999 to 2005', 2 July 1999; and RIA Novosti (2004) 'Bioterrorism Threatening Humankind', *RIA Novosti*, 26 July.

Raevsky, K. K. (2002) [Highest Priority Measures for Creating a System to Counter Biological Terrorism], Military Medical Academy, Military Prevention Medicine: Problems and Perspectives, Proceedings of the First Congress on Military Medical Programs in the Armed Forces of the Russian Federation, St Petersburg] (in Russian), pp. 75-7, translated in Appendix H, pp. 108-12 (2006) in NAS (2006) *Biological Science and Biotechnology in Russia*; and President of Russian Federation V. V. Putin (2003) 'The Foundations of the State Policy for Ensuring Chemical and Biological Safety of the Russian Federation for the Period up to 2010 and Longer Terms', approved on 4 December 2003, No. Pr-2194, in *Analysis of the Existing Chemicals Management System in the Russian Federation*, Unofficial translation in Baltic Environmental Forum, Nordic Council, October 2004–December 2005, on the Internet: http://www.norden.org/pub/miljo/miljo/wlk/US2006416.pdf (retrieved 29 February 2008).

Agency (three). A primary aim was to carry out a comprehensive survey of biological and chemical safety and security in the Russian Federation and then develop appropriate regulations and reducing risks. To this was added raising awareness and establishing a scientific base to improve biological security. There have been examples of attempted thefts even at the well protected Virology and Biotechnology Centre Vector in Koltsovo in 2010. Since 2006, the ministries and agencies have reported annually on the measures they have taken to reduce risks associated with natural outbreaks of infectious diseases or intentional dissemination of biological agents or chemical substances. Many of the actions carried out against bioterrorism were coordinated with other actions in the fight against infectious diseases. This included activities such as epidemiological surveillance and preventive treatment, vaccination, improvement of laboratory quality and technical resources, and support to research into diagnosis, epidemiology and medical protection against infectious diseases.

Russia has a R&D programme to protect against biological weapons in the Ministry of Defence's Institute of Microbiology, at three locations – Kirov, Sergiev Posad and Yekaterinburg. In the first years of the 21st century, the budget has increased and the programme is still the world's second-largest after that of the U.S. The number of people involved in the programme has not changed significantly since the year 2000, when it was around 2500. There is still only very limited information on the biological defence research and development being carried out at the Ministry of Defence facilities. At the Institute of Virology in Sergiev Posad a special centre was created for specific laboratory diagnosis and treatment of highly dangerous diseases, including protection against terrorist activities. A second centre for the control of bioterrorism has been placed at the Volgograd Anti-plague Institute under the Ministry of Health and Social Development. Both these institutes had important functions in the earlier biological weapons programme. To prevent uses other than for peaceful purposes, the export of dual-use materials.

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Russian Federation (2008) 'On the Federal Target Program, The National System of Chemical and Biological Security of the Russian Federation (2009–2013 years)', Resolution from 27 October 2008, No. 791, on the Internet: http://www.garant.ru/prime/20081106/2066728.htm (retrieved 11 March 2009); and RIA Novosti, 'Russia Approves Chemical and Biological Security Programme Concept', *RIA Novosti*, 1 February 2008 (translated by NTIS, U.S. Deptartment of Commerce).

¹⁰² Interfax (2010) 'Interior Troops Prevent Theft of Sensitive Info from Virology Laboratory', Interfax-AVN online, 11 March 2010.

Onishchenko, Gennady G. et al. (2003) 'Bioterrorism: A National and Global Threat', Vesnik Akademii Nauk, Vol. 73, No. 3 (March), pp. 195-204, translated in Appendix G, p. 106, in NAS (2006) Biological Science and Biotechnology in Russia.

Evaluation Based on the Russian Reports Submitted to the UN in the Framework of the Confidence-Building Measures under the BTWC.

Westerdahl, Kristina S. and Lena Norlander (2006) The Role of the New Russian Antibioterrorism Centres, FOI Report 1971 (Umeå, FOI).

equipment and know-how is monitored and controlled in line with international agreements and in accordance with Russian legislation.

3.1 The Centre for Military Technical Problems of Biological Defence at Yekaterinburg

The Centre for Military Technical Problems of Biological Defence, a branch of the Federal State Establishment (FGU) 48th Central Scientific Research Institute of the Russian Federation's Ministry of Defence, has during its 60 years changed its name six times but it has become commonly known as the 19th Military Base. It was established in July 1949 by a Decree of the USSR Council of Ministers, the USSR war minister, Marshal of the Soviet Union Aleksander Vasilevskiy, issued an order directing that a separate troop unit be formed at the Sverdlovsk-Cherkassk Infantry School 'for solving problems to ensure the anti-biological protection of personnel and the nation's population'. Major General Nikolay Kopylov was appointed the first commander of the unit, the Scientific Research Institute of Hygiene of the USSR War Ministry. A unique laboratory was established and equipped with the latest equipment, both domestically-produced and of foreign manufacture. Initially the microbiology, biochemistry, and immunology of botulinum toxins of various types, as well as to resolve issues relating to the mass immunization of people were studied.

Today, the Centre's post is an independent garrison within the Yekaterinburg garrison. The Centre carries out research and experimental work to develop means and methods of biological defence for the Armed Forces and for the nation's population. The Centre has developed a whole series of vaccines for a number of infectious diseases, and has also developed diagnostic products and disinfectants. A well known immunological compound called Biosporin was developed with primary applications for the treatment of acute forms of intestinal infections. The microorganisms in Biosporin produce a number of bioactive substances that have antibacterial and antiviral properties that can strengthen the immunity response against variety of infectious diseases. The centre continues to develop new drugs and methods for the Ministry of Defence, Russian Agency for State Reserves, Ministry of Health and Social Development, and other government departments. In addition the centre has developed methods for cleaning oil-contaminated areas, using a compound called Tsentrin based on microorganisms. Numerous trials and real-life application have been carried out. 106

http://www.redstar.ru/2010/03/10_03/2_04.html (retrieved 8 April 2010)

Belousov Yuriy (2010) 'Russia: History, Current Work of Centre Countering Biological Warfare Toxins', Krasnaya Zvezda, online official newspaper of the Ministry of Defence, Red Star (in Russian) [Site 19] (Translation provided by OSC) 10 March 2010, on the Internet:

4 International Cooperation and Threat Reduction, Programmes in Biotechnology

After the collapse of the Soviet Union, funding fell dramatically for all research, including in biotechnology. As a consequence of this, the American Academy of Sciences initiated a collaboration programme to 'save' the Russian natural sciences. Around 1991 Russia did not give priority to research. Many researchers looked for other ways to make money, which is why many abandoned their research careers. Western countries became aware that the lack of security in Russia and at research institutes was a concern to be taken seriously, as there was an increasing risk that material and knowledge related to weapons of mass destruction could end up in the wrong hands and be misused. Western countries, especially the United States, initiated various types of financial support as part of the so-called Cooperative Threat Reduction Programs (CTR). The purpose of these programmes, initiated in the early 1990s, was to prevent material from being diverted abroad and to improve security at facilities of concern. An important aim was to prevent former weapon scientists with knowledge related to weapons of mass destruction, including biological weapons, leaving Russia because of their dire financial situation. Less scrupulous regimes with the ambition to develop biological weapons could take advantage of the situation. With time, more countries joined these cooperation programmes, among them the member states of the European Union. Different arrangements were created to coordinate donor support and the G8 became an important forum for coordination. 107 These support programmes were also important in transforming Russian science funding towards a system based on competition between scientists for grants, which did not exist in the Soviet system. Several governmental and non-governmental foundations for financing research, relying on peer review and grant competition, were established. 108

Cooperation was initially focused on the nuclear area, but later it also emphasized the chemical and biological areas. During the more than fifteen years that the programmes have existed, most efforts have focused on security in the nuclear field and the destruction of old chemical munitions. In the biological

¹⁰⁷ G8 Summit (2007) 'Heiligendamm Statement on Non-proliferation', on the Internet: http://www.g8.utoronto.ca/summit/2007heiligendamm/g8-2007-nonprolif.pdf (retrieved 3 September 2007); and G8 Summit Heiligendamm (2007) 'GPWG Annual Report 2007, Consolidated Report Data', Annex A, on the Internet:

http://www.g8.utoronto.ca/summit/2007heiligendamm/g8-2007-gp-report-anx.pdf (retrieved 3 September 2007).

Gerber, Theodore P. and Deborah Y. Ball (2008) Scientists in a Changed Institutional Environment: Subjective adaptation and social responsibility norms in Russia, 27 June, Lawrence Livermore National Laboratory, Report LLNL-JRNL-405009.

field, much was done in the former Soviet republics, with which there was good cooperation. It was more difficult to make progress in Russia. One reason was that Russia has not been willing to admit or to declare in public details of its previous activities, such as the scientists or the facilities, involved in the Soviet Union's programme to develop biological weapons. ¹⁰⁹ It was easier to collaborate with interested governments in the other former Soviet republics, including the states in the Caucasus and Central Asia. The support was aimed mainly at former weapons scientists and at strengthening security around the facilities to prevent terrorists from getting hold of dangerous pathogenic agents.

In order to facilitate international research cooperation and to channel the financial assistance, two international centres were established – the International Science and Technology Centre (ISTC)¹¹⁰ in Moscow, and the Science and Technology Centre Ukraine (STCU)¹¹¹ in Kiev. The proportion of projects financed under the biological or biotechnological area was initially small but over the years it has grown in scope. The support provided by these centres has played a major role in persuading researchers to remain in research and not to leave the country, as well as in developing biotechnology in Russia during a financially difficult period. Much of the research in Russian biotechnology and medicine has been partly funded through the ISTC, which has provided via donor countries approximately \$40 million annually. 112 Initially the support focused on the institutes belonging to the Biopreparat organization, including the institutes in Obolensk and Koltsovo. Over the years these institutes have obtained a large part of the financial assistance in the light of the fact that they worked on very dangerous infectious agents. One drawback was that no facilities or researchers at the Ministry of Defence facilities or the Ministry of Health anti-plague institutes were permitted by the Russian government to take part in the international threat reduction cooperation.

Questions concerning biological safety and security have been central in the cooperation programmes, not least after the terrorist attack against the World Trade Center and Pentagon in the U.S. in September 2001. At the time, many companies in the West believed that good technology, facilities and expertise were available in Russia. The parties in the West involved often had too high expectations so the outcome and the benefits did not meet their expectations. The salaries of researchers were low and the head of an institute earned about \$200

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Roffey, R. (2008) EU–Russian Partnership to Reduce Bio-Threats and Fight Disease Outbreaks, Report FOI R-2493-SE, March (Stockholm, FOI).

Annual Report 2006, International Science and Technology Centre, ISTC, Moscow, on the Internet: http://istc.ru/ISTC/sc.nsf/AR-2006-en.pdf (retrieved 21 September 2008).

Annual Report 2006, Science and Technology Centre Ukraine, STCU, on the Internet: http://www.stcu.int/documents/stcu_inf/reports/annual/2006/ (retrieved 2008-09-21).

Abercade Consulting, 'Sources of Funding Biotech Projects in Russia', Report, on the Internet: http://www.abercade.ru (retrieved 21 January 2008).

per month in 2003 and a senior researcher \$150 per month. 113 A development that was worrying some American and Russian scientists was that the proportion of applied research was increasing at the expense of basic research; ¹¹⁴ this was probably an effort by the involved Russian scientists to focus their research on areas that could best provide commercial dividends and profits. 115

One area that has been of concern has been the depositories with smallpox virus at CDC in the U.S. and at Vector in Novosibirsk. There has been a long discussion about whether the remaining stocks should be destroyed. In 2006, Russia, the U.S. and a few other countries blocked a draft World Health Organization (WHO) resolution setting a timeline for destruction at 2010. In 2007, the WHO World Health Assembly adopted resolution 60.1, indicating that there was a need to reach a consensus on the destruction of remaining stocks of the smallpox virus when research outcomes crucial for public health concerns to counter a potential outbreak so permit. The aim was to reach an agreement in 2011 and after the WHO had carried out a major review of research performed. In the framework of the U.S. CTR programme, the U.S. proposed three research projects to be carried out in collaboration with Russia, which would include U.S. scientists working at Vector in order to increase the transparency of this research, in 2004. These projects were never started in spite of U.S. pressure and since then the transparency of Vector's smallpox research has decreased significantly. Research on testing anti-virus drugs against live smallpox has been resumed at Vector. There are still U.S. suspicions that smallpox virus are also stored at the Ministry of Defence facility in Sergiev Posad. 116 It has been reported that scientists at Vector were not permitted to have contacts with foreign scientists or journalists from 2005 when I. G. Drozdov was appointed as director. This has also been followed by many scientists leaving Vector. There has also been sent a protest letter to President Medvedev concerning economic irregularities at Vector. 117

The increased difficulties encountered by the U.S. Department of Defense (DoD) when cooperating with Russia in the biological area led it to reduce its financial support for CTR activities in this area in Russia significantly between 2000 and

¹¹³ NAS (2006) 'Pillar Two: Meeting pathogen research challenges', p. 40, in *Biological Science* and Biotechnology in Russia.

Basic research is driven by a scientist's curiosity or interest in a scientific question. The main motivation is to expand man's knowledge, not to create or invent something. The research is not driven by any obvious commercial value to the discoveries that result from basic research.

¹¹⁵ Roffey (2008) EU–Russian Partnership.

¹¹⁶ Tucker, Jonathan B. (2009) 'The Smallpox Destruction Debate: Could a grand bargain settle the

issue?' *Arms Control Today*, March.

117 Korchagin, Pavel (2010) 'Russia: Open Letter to Medvedev Alleges Corruption at Koltsovo Virology Center Open letter to the Russian president from Pavel Korchagin, deputy of the settlement council of the Koltsovo Science City in Novosibirsk Oblast', preceded by Novaya Gazeta editorial introduction: "A 'Laundry' Marked 'Secret'? Millions of Budget Rubles Dissolved at the Vektor Virology Center in Siberia" Novaya Gazeta Online, April 7, 2010.

2009. It has been suggested that the CTR programme in this area would have been more successful in Russia if the DoD had not been the lead body for U.S. Government support. Other U.S. government departments have been able to continue their cooperation with Russia. 118

For a more in-depth discussion of threat reduction activities in the biological area, see Roffey (2008) EU–Russian Partnership.

5 Russian–EU Collaboration in the Area of Biotechnology R&D

The trend has been to increase R&D cooperation with Russia in the form of partnerships and to decrease technical assistance in the form of threat reduction programmes in the 21st century. There is a good base for cooperation between the EU and Russia in the form of the Partnership and Cooperation Agreement (PCA), with Four Common Spaces to encourage political, commercial, economic and cultural cooperation between Russia and the EU. ¹¹⁹ There is a so-called Roadmap for the EU-Russia Common Space in Research and Education including Cultural Aspects from 2005. There are regular meetings between relevant ministries and the European Commission, a joint committee for cooperation which meets annually (Joint EU-Russia S&T Cooperation Committee), and joint thematic working groups in areas such as nanotechnology, health, and biotechnology for food and agriculture, in addition to regular meetings of experts. The BILAT-RUS project was launched in 2008 aimed at contributing to the implementation of the Common Space on Research. ¹²⁰ The aim was to intensify the dialogue with the EU on R&D where the Russian priorities for cooperation were: ¹²¹

- Information, telecommunications and electronics;
- Nanotechnologies and materials;
- Life sciences;
- Environmental protection and management of the environment;
- Energy and energy saving;
- Security and antiterrorism; and
- Advanced machinery and equipment.

The European Union has concluded nine partnership and cooperation agreements (PCAs) with countries of Eastern Europe, the Southern Caucasus and Central Asia. The aim of these agreements is to strengthen their democracies and develop their economies through cooperation in a wide range of areas and through political dialogue. A Cooperation Council has been set up to ensure implementation of the agreements, on the Internet:

http://europa.eu/legislation_summaries/external_relations/relations_with_third_countries/eastern_europe_and_central_asia/r17002_en.htm (retrieved 10 March 2010).

Russian National Contact Point (RNCP) on Biotechnology, Food and Agriculture, on the Internet: http://www.fp7-bio.ru/en/fp7-projects-of-russia/bilat-rus/ (retrieved 20 October 2009); and BILAT-RUS: Enhancing the Bilateral S&T Partnership with the Russian Federation, FP7 Program, ZSI Centre for Social Innovation, on the Internet:

http://www.zsi.at/en/projekte/4961.html (retrieved 20 October 2009).

Eryomin, Vladimir (2008) 'Russian National Contact Point (Bio-NCP) on Food, Agriculture, Fisheries & Biotechnology, Institutional, Legal and Financial Environment for Russian Researchers (Institutes of RAS, Universities) – Opportunities and challenges for EU–Russian cooperation in FP7 and FAFB priorities', Presentation at the International Training Workshop, 2nd RUSERA-EXE Training Course, 1 February 2008, Vienna, Austria, on the Internet: http://rp7.ffg.at/upload/medialibrary/02-Eryomin.pdf (retrieved 10 March 2009).

The EU and Russia have been pursuing cooperation in science and technology since 1994. Initially, Russian research organizations gained access to limited parts of the EU S&T (science and technology) programmes. Thus, the INCO Copernicus-2 Programme was specially launched within the Fifth Framework Programme (FP5) in order to establish S&T collaboration between the EU member states and the countries of Central and Eastern Europe and the Commonwealth of Independent States (CIS) countries. In order to improve the participation of Russian scientists and researchers in the EU's Framework Programmes, a network of national contact points (NCPs), including one for the biotechnology area (Bio-NCP), was set up in Russia and has been operating since 2004 in accordance with a regulation by the Russian Ministry of Education and Science. The aim was to promote the integration of Russian science into the European Research Area (ERA) by participation in the EU Framework Programmes (FP7). The Russian NCP networks have been key elements of support for the EU-Russia S&T cooperation. 123

European and Russian scientists and research organizations have worked together in all areas of science in many bilateral programmes of the 27 EU member states, in the context of programmes funded and managed by the European Union (such as the EU Framework Programmes for Research & Technological Development, and the TACIS, Technical Assistance for the Commonwealth of Independent States), as well as through pan-European science organizations (such as INTAS, EUREKA, COST, and the European Science Foundation) and international organizations and initiatives (such as CERN, the ISTC, and ITER). Many EU member states had bilateral intergovernmental or inter-institutional cooperation agreements with Russia, among them Germany, France, the UK and the Netherlands. 124 Germany had active cooperation with Russia in the area of biotechnology, often resulting in common FP7 proposals. The German Ministry of Science and Education promoted cooperation in biology and biotechnology for 2010. A Joint Laboratory Biakal was established with a focus on molecular biology and sustainable exploitation of endemic sponges. Promising areas for cooperation were:

http://ec.europa.eu/research/iscp/pdf/russia.pdf (retrieved 10 March 2010).

¹²² Ibid.

¹²³ European Commission (2009) Compendium on Science & Research Cooperation between the European Union and the Russian Federation, on the Internet:

libid.; and Sandhop, Martin (2008) The Russia-Co-operation of the International Bureau of the BMBF: Funding Policy, Tools, and Prospects, Federal Ministry of Education and Research, on the Internet:

http://www.owwz.de/fileadmin/Biotechnologie/BioVeranst/Pushchino 2008/Sandhop.pdf (retrieved 19 March 2009).

¹²⁵ Burghardt, Nicole and Gabriele Gorzka (2007) 'German–Russian Cooperation Network Biotechnology', Journal of Biotechnology, Vol. 2, pp. 780-1; Forschung und Innovation (2009) 'Die Strategische Partnerschaft Deutschland-Russland in Bildung', Forschung und Innovation, on

- Genomics and proteomics;
- Pharmaceuticals and medical engineering;
- Agriculture and food biotechnology;
- Bioinformatics; and
- Molecular biology.

At the same time, Russian research programmes and foundations, such as the Russian Federal Targeted Programme for Research & Development, the Russian Foundation for Basic Research (RFBR), the Foundation to Support the Development of Small-Scale Enterprises in Science & Technology, and the Russian Foundation for the Humanities (RFH), have increasingly reached out to their European partners to involve them in their activities. 126

Table 2. Prospective Areas for EU– Russian S&T Cooperation 2009
 Primary areas of the Federal Targeted Programme Thematic Areas of the EU's Seventh R&D in Priority Areas of Russia's Scientific Framework Programme for Research and Technological Development in 2007-2012 and Technological Development 2007-2013 • Health Life Sciences Food, Agriculture and Biotechnology · Industry of Nanosystems and Materials · Nanosciences, Nanotechnologies, Materials and Production Technologies Information & Telecommunication Systems • Information & Communication Technologies • Sustainable Use of the Environment • Environment (including climate change) · Energy and Energy Efficiency Energy • Transport (including Aeronautics) Socio-economic sciences and Humanities • Space Security

The Russian R&D programme for EU cooperation consisted of five major blocks, as seen in Table 2, and it had a total budget 2009 of 195 billion roubles, including 21.3 billion roubles to be allocated for the projects jointly implemented with foreign partners. This Federal Targeted Programme provided opportunities for all interested entities, including foreign organizations, to implement promising R&D drawing on Russian federal budget funding. The prospective areas for EU-Russia collaboration are outlined in table 2 for comparison.

Russia adopted the European Concept of Technology Platforms, based on the European Knowledge-Based Bio Economy, by creating similar platforms in Russia. ¹²⁷ The established platforms in Russia were food quality and safety, The Russian R&D programme for EU cooperation consisted of five major blocks, as

the Internet: http://www.deutsch-russische-partnerschaft.de (retrieved 15 October 2009); and Sandhop (2008) The Russia-Co-operation of the International Bureau of the BMBF.

European Commission (2009) Compendium on Science & Research Cooperation between the European Union and the Russian Federation.

Eryomin, Vladimir (2008) 'Russian National Contact Point (Bio-NCP)'.

seen in Table 2, and it had a total budget 2009 of 195 billion roubles, including 21.3 billion roubles to be allocated for the projects jointly implemented with foreign partners. This Federal Targeted Programme provided opportunities for all interested entities, including foreign organizations, to implement promising R&D drawing on Russian federal budget funding. The prospective areas for EU-Russia collaboration are outlined in table 2 for comparison: industrial biotechnology, forestry, plants for the future, animal health, fisheries and biofuels. From 2008, a jointly funded programme in industrial biotechnology was initiated. It focused on new generations of industrial enzymes, bio-plastics, bio-binders and biocatalysts. It also covered process design, biofuels, and bio-remediation. The Russian national priorities for cooperation in biotechnology were:

- Bioengineering;
- Bio-informatics;
- Cell technologies, including stem cells;
- Biosensors;
- Biomedical technologies;
- Genomic and post genomics for drug development; and
- Bio-catalysts and biosynthetic technologies.

A review of the Russian participation in the EU Sixth European Framework Programme (FP6) showed that, of a total of 2372 organizations that submitted proposals, 442 were accepted. Russia was the third largest country (outside the EU and excluding associated states) within the FP6 for research. Russia participated in 200 projects with a value of €2000 million, of which Russia contributed €16 million and the European Commission the remainder. Russia participated in several areas including the environment, sustainable development, IT, nanotechnology, genomics, and biotechnology focused on health and food quality. Cooperation in the areas of food, agriculture, fisheries and biotechnology within the framework of FP6 has involved 12 partners from Russia in a total of 12 projects. Overall, Russia had an average success rate of 19.3 per cent and Russian partners received a total of €1.3 million of European Commission funding.

In the European Framework Programme FP7, 24 partners from Russia participated in the first four calls in the period 2007–2009. Russia ranks second in success rate for receiving grants among all third countries successfully participating, and the overall success rate for Russia was 18.8 per cent applied

¹²⁸ CORDIS (2007) 'EU and Russia to Strengthen Agrobio-food Research Ties', Eurosciences, Press Release, 18 September 2007, on the Internet: http://www.lswn.it/en/press_releases (retrieved 26 February 2008).

Minch, Mary (2007) 'Presentation, European Community Framework Programme for Research & Technological Development 2007–2013', The EC–Russian Dimension, European Commission, on the Internet: http://www.hse.ru/temp/2007/files/02_22_konf/Minch.ppt (retrieved 26 February 2008).

projects granted. In total, 128 partners from Russia participated in submitting proposals under the first four calls in FP7, with a high participation in call 2B, under which the EU-Russia coordinated call in Biotechnologies was carried out, with the selection of two co-funded projects. From the Russian side for 2008, around 25 per cent of the funding was allocated for EU cooperation in life sciences and biotechnology. ¹³¹ However, after a remarkable success in 2008, the participation of Russia decreased significantly in 2009 (one selected partner, with success rate of 6 per cent). The EU and Russia are working towards Russia being able to join the EU's FP7 as an associate member. 133 Within FP7, joint (Russia-EU) tenders have been announced in the fields of energy and biotechnology where companies and organizations from France, Germany and the Netherlands are taking part. 134 There were also initiatives aimed at increasing the quantity and quality of cooperation between Russian and EU researchers by joint project proposals within the FP7, or publications in scientific journals, presentations at conferences, holding joint thematic workshops, patents and so on. 135

The Gate to Russian Business and Innovation Network (Gate2RuBin¹³⁶) was created to assist the development of business and technological cooperation between SMEs (small and medium-sized enterprises) and R&D organizations in Russia and inside the EU. 137 The project was implemented by a consortium of three network organizations: the Russian Agency for Support of Small and Medium Business (RA), the Union of Innovation Technology Centres of Russia (RUITC), and the non-profit partnership Russian Technology Transfer Network

¹³⁰ Ibid.

Russian Platforms, EU FP7 (2009) 'Russian National Contact Point (RNCP) on Biotechnology, Agriculture and Food Coordination', on the Internet: http://www.fp7-

bio.ru/copy of platformy/rossiiskie-platformy (retrieved 23 February 2009).

European Commission (2009) 'European Community–Russia'.

133 'EU/RUSSIA: Moscow eyeing associate membership in FP 7', 23 June 2008, on the Internet: http://www.encyclopedia.com/doc/1G1-180842535.html (retrieved 8 March 2010).

Rossiiskaia Gazeta (2008) Interview with Sergei Mazurenko, the head of Federal Agency on Science and Innovation, who has shared his thoughts on changing the role of Russian science and Russian scientists in international cooperation and the global scientific community. Rossiiskaia Gazeta, Federal issue No. 4572, 25 January, on the Internet:

http://www.eurasiabio.org/media/news/page-4/ (retrieved 10 March 2010).

Rusera-exe project, on the Internet: http://www.rusera-exe.ru/index_en.php (retrieved 1 October 2009).

¹³⁶ Gate2RuBin (2009) Discover the Russian Innovation Cooperation Potential, Brokerage Meeting Catalogue, Gate2RuBin – Enterprise Europe Network Correspondence Center in Russia, Moscow, October 2009, on the internet: http://www.gate2rubin.net/ files/news/n769 G2R%20-%20Brokerage%20Meeting%20Catalouge.pdf (retrieved 10 March 2010).

Enterprise Europe Network, Gate to Russian Business and Innovation Networks (Gate2RuBIN), on the Internet: http://www.euroinfocenter.ru/eicc-EN/index.php?do=static&page=gate2rubin (retrieved 10 October 2009).

(RTTN).¹³⁸ The European Federation of Biotechnology (EFB) supports cooperation with Russia in the FP7 and opened an office in Moscow in 2006, at the Russian Society of Biotechnologists. Russian scientists were then able to cooperate on equal terms with EU scientists.¹³⁹

The EU-Russia science cooperation was, and continues to be, seen by the European Commission as a success story. According to Andrei Fursenko, Minister of Education and Science of the Russian Federation, cooperation between the European Union and the Russian Federation in science and research is one of the most successful and most dynamic areas of EU-Russia relations. The cooperation was working well on the evidence of interviews with researchers, although language problems were a difficulty. The hierarchical system in Russian research institutes was causing delays, and lack of Russian funding and lack of project management on the Russian side were also highlighted as problems. Opinion polls conducted in August 2001 and January 2007 showed an increase from 35 to 50 per cent of respondents with university degree who felt that Russian higher education is not as good as the equivalent education internationally.

Where the area of R&D cooperation between Russia and EU is concerned, it can be noted that this cooperation seems to be growing and fruitful for both parties, not least in the EU Framework Programmes. The number of partners in Russia increased between FP6 and FP7. This is also true for the biotechnology area even if there seems to have been a setback during 2009. The reason why so few Russian entities submitted proposals was not clear. One positive sign was that Russia is also funding this research so it was not a question of financial support for research only. For the modernization of the Russian innovation system and for high-tech research it will be important to develop further this and other initiatives for international cooperation in R&D. One conclusion is that this area seems to be one of the few where EU-Russian cooperation is working fairly well.

Russian National Contact Point on Biotechnology, Framework Program 7, on the Internet: http://www.fp7-bio.ru/en/fp7-projects-of-russia/gate2rubin/ (retrieved 10 October 2009).

¹³⁹ 'Interview with Charles Bryce, Vice-President of the European Federation of Biotechnology', 2006.

¹⁴⁰ European Commission (2009) 'European Community–Russia'.

European Commission (2009) Compendium on Science & Research.

CORDIS (2009) 'EU–Russian Research Cooperation Good But Could Be Better, Says Report',
 Community Research and Development Information Service – CORDIS', 9 July 2007, on the
 Internet: http://cordis.europa.eu (retrieved 20 November 2009).

Population Poll (2007) 'The Quality of Higher Education in Russia', 25 January, Public Opinion Database, on the Internet:

http://bd.english.fom.ru/report/map/projects/dominant/edom0704/edomm0704_2/ed070421 (retrieved 23 April 2007).

6 The Russian Innovation System

The vision of the Russian government, according to the Ministry of Economic Development's Concept of Long-Term Development of Russia, approved by Vladimir Putin in November 2008, was that Russia by 2020 should become the fifth leading economy in the world. The Concept pointed out the need to strengthen the role of innovation in order to sustain economic growth, and one of the goals was said to be to create a competitive innovation economy. Budget figures in the research sector were clear: while the Soviet research budget amounted to 2.9 per cent of gross domestic product (GDP) in 1990, it had fallen to 1.3 per cent of a much smaller GDP at the end of the 1990s and in 2006 amounted to 1.6 per cent (of a larger GDP), while the average of the OECD countries was at 2.7 per cent of GDP. A Russia spends one-seventh of what Japan spends and one-seventeenth of what the U.S. spends on science. Russia's share of the global high-tech markets was estimated to be 0.2–0.3 per cent in 2009.

Table 3. Ministry of Education (2008)	Required Structural Shift in the Economy
and Stimulation of Innovations ¹⁴⁶	

Areas	2005	2010
Share of raw materials sector in GDP	40%	20%
Share of high-tech products in Russia's total exports	0.3-0.5%	0.9–1.5
Industry enterprises implementing innovations	10%	25–30%
Specific yield of shipped innovation products	9.5%	25–30%
Share of intangible assets involved in economic turnover	1%	30%

¹⁴⁴ Leijonhielm, Jan et al. (2009) 'HIV/AIDS – ett underskattat problem' [HIV/AIDS: An underestimated problem], pp. 110-11, in *Rysk militär förmåga i ett tioårsperspektiv: ambitioner och utmaningar 2008* [Russian Military Capacity in a Ten-year Perspective: Ambitions and challenges 2008], Report FOI-R--2707--SE (Stockholm, FOI).

¹⁴⁵ Kuzyk, B. N. (2009) 'Russia's Innovation Development: A scenario approach', Herald of the Russian Academy of Sciences, Vol. 79, No. 3, pp. 216-24, on the Internet: http://www.springerlink.com/content/28310242w7371134/fulltext.pdf?page=1 (retrieved 10 March 2010).

Ministry of Education (2008) as quoted by Mezenova, Olga (2008) 'Biotechnology in Russia: Innovation sectors in research and industry', Russian Society of Biotechnologists, Presentation at German Russian Workshop in Biotechnology, Hanover, on the Internet: http://www.owwz.de/fileadmin/Biotechnologie/BioVeranst/Biotechnica_2008/Mezenova.pdf (retrieved 10 March 2009).

The Ministry of Education and Science indicated in 2008 that there was a need to achieve a structural shift in the economy to promote innovation (see Table 3). President Medvedev has said that the task of transforming the national economy based on innovation had largely failed. Further, in an article entitled 'Go Russia' in September 2008, Medvedev stated: 148

Russia will take a leading position in the production of certain types of medical equipment, sophisticated diagnostic tools, medicines for the treatment of viral, cardiovascular, and neurological diseases and cancer. We will encourage and promote scientific and technological creativity. First and foremost, we will support young scientists and inventors. ... Public and private companies will receive full support in all endeavours that create a demand for innovative products. Foreign companies and research organisations will be offered the most favourable conditions for establishing research and design centres in Russia. We will hire the best scientists and engineers from around the world.

Research and development funding from the Russian federal budget was \$1.3 billion in 2002, \$2.2 billion in 2005, \$3.5 billion in 2007 and \$5.4 billion in 2009. The plan for 2010 was to reach \$6.8 billion (this was before the effects of the financial crisis were felt). In comparison with Western countries, which were investing around 7–25 per cent (in the case of Sweden 15 per cent) of their industrial research expenditure in pharmaceuticals R&D, Russia spends only 1 per cent of its industrial research funding on pharmaceuticals. In addition, Russia spent very little of its total academic research funding on medical research: in Russia the share was about 2 per cent, in the U.S. it was around 28 per cent, and in Sweden it was approximately 27 per cent in 2006.

¹⁴⁷ RIA Novosti, 31 August 2009.

Medvedev, Dmitry (2009) 'Go Russia!', The Kremlin, 10 September 2009, on the Internet: http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009).

Russian Ministry of Education data, 2008.

¹⁵⁰ NAS (2006) 'Pillar Three, The Promise of Biotechnology', in *Biological Science and Biotechnology in Russia, Controlling Diseases and Enhancing Security* (Washington, DC, National Research Council of the National Academies, NAS Press), p. 54.

¹⁵¹ NAS (2006) 'Pillar Two, Meeting Pathogen Research Challenges', in *Biological Science and Biotechnology in Russia*, p. 41.

Historical developments

1992—1996 attempts made to preserve science during period of economic crisis, creation of new organisations and institutional frameworks.

1997—**2001** frequent changes made in science and innovation policies, development of innovation infrastructure.

2002—2007 development of strategic visions for science and innovation policies, attempts made to initiate structural reformas in science and create a more favourable climate for innovations.

Small international biopharmaceuticals development companies have begun seeking out Russian partners independent of government partnering help. However, Russia's business climate is still immature, which could make such partnerships challenging and difficult for foreign companies. In the past, most international licensing deals have been brokered by the ISTC in Moscow. According to the Federal Agency for Management of Special Economic Zones, the major concerns of investors are bureaucracy and administrative problems, difficult visa procedures, security of ownership rights, limited reaction to investors' needs and lack of information on Russia. 152 The lack of adequate protection of IPR (intellectual property rights) is still a major obstacle for the development of Russia's biotechnology industry. The number of patents granted per one millon of the population was 1 for Russia, 78 for Western Europe and 328 for U.S. 2001-2005. ¹⁵³ As late as the 1990s, all patents were the property of the government, giving no incentive for the general public to protect and care for individuals' inventions. IP enforcement is still weak in Russia - something that both the U.S. and the EU have stressed in negotiations on Russian accession to the WTO (World Trade Organization). 154 To a great degree, the difficulty stems from the absence of precedents for interpreting laws relating to patents and the free-market economy, most of which are barely a decade old. Especially outside urban centres like Moscow and St Petersburg, judges and lawyers tend to be less experienced in dealing with international trade issues relating to exports or

152 'Special Economic Zones: A new tool for improvement of investment climate in Russia', Federal Agency for Management of Special Economic Zones, Presentation, 2007.

Katsnelson, Alla (2004) 'Russia Becomes Attractive as a Source of IP for Biotechs', *Nature Biotechnology*, Vol. 22, No. 9, p. 1060.

Dezhina, Irina (2008) Russian Science Policy in Post-Soviet Period, Institute for World Ecobony and International Relations, RAS, Presentation, on the Internet:
http://www.globelicsacademy.net/2008/2008 prof presentations/GA08%20Lecture%207.pps#25
6 (retrieved 20 March 2010).

arbitration. ¹⁵⁵ It should, however, be mentioned that in the first years of the 21st century the patent framework in Russia has been significantly improved. ¹⁵⁶ This is important for the development of applications in biotechnology. Russia has recognized that the earlier laws were outdated and needed to be improved. The government has cancelled 54 older laws, and has committed itself to the preparation of a new intellectual property legal regime which would include four laws and sixteen governmental decrees. In the Duma a Council for Science, Technology and Innovation was established in 2008 and destined to work as an expert advisory body.

The recovery from the lack of R&D funding in the 1990s has so far been too slow. 157 A satisfactory mechanism to distinguish high-quality research from inferior research was still needed. 158 From 1992 to 2002 a new system was developed for the selection of research projects by which scientists would receive funding based on a system of 'peer review'. After 2003, this was unfortunately replaced by an administrative system in which the organization and the applicants' position had once again become the most important basis for funding, and not the quality of research. It was back to the previous system where the heads of institutes were negotiating on the allocation and it appears to benefit mainly institutes in Moscow and St Petersburg. 159 The number of scientists per 10 000 was 74 in 2000 which had decreased to 59 in 2006. If assessed as per cent of number of scientists 1991 the number was 45 per cent in 2006. There was still in 2009 a trend of decreasing number of scientists due to emigration. The age structure of scientists were in 2006: younger than 29 years 17 per cent, 30-39 years 13 per cent, 40-49 years 19 per cent, 50-59 years 28 per cent and over 60 years 32 per cent. 160 The average age of scientists with doctorial degree in Russia was 61 years in 2008.161

Nature Biotechnology (2004) 'Russian Biotech Needs Better Patent Protection, Bioentrepreneur' (2004) Nature Biotechnology, 5 August, on the Internet:

http://www.nature.com/bioent/bioenews/082004/full/bioent823.html (retrieved 15 March 2007).

The main body of intellectual property law in Russia consists of the Russian Citizens' Code of 1964, the Patent Law of Russia (1992) and the Law for the Rights of Innovators.

¹⁵⁷ Ivanova, Natalia et al. (2007) INNO-Policy TrendChart – Policy Trends and Appraisal Report (Brussels, European Commission, DG Enterprise); Gerber and Ball (2008) Scientists in a Changed Institutional Environment; and Carnegie Endowment for International Peace (2002) Russian Basic Science After Ten Years of Transition and Foreign Support, Carnegie Paper No. 24, February.

Feigelman, M. (2007) 'What the Scientists Say', *Nature*, Vol. 449 (4 October), p. 529.

Lyakhovich, S. (2007) 'What the Scientists Say', *Nature*, Vol. 449 (4 October), p. 529.

¹⁶⁰ Dezhina (2008) 'Russian Science Policy',

¹⁶¹ Yegerov, Igor (2009) 'Post-Soviet Science', pp.600-9.

In the Basic Principles of the Russian Federation's Policy on the Development of Science and Technology for the Period to 2010 and beyond, to reach the state's policy objective it would be necessary to: 162

- establish mechanisms for enhancing demand for innovations based on advanced fundamental science and the most important kinds of applied R&D;
- improve the normative legal basis for scientific, technical and innovative activities adapting the scientific–technical complex to a market economy;
- combine state regulatory and market mechanisms for the direct and indirect encouragement of innovation;
- improve the training system for highly skilled scientific and engineering personnel;
- strengthen the R&D capabilities of higher education institutions;
- facilitate a more active exchange of knowledge and technology between the
 defence and civilian sectors of the economy, and the development of dual-use
 technologies for wider application;
- develop and modernize weapons and military/special equipment; encourage the development of the defence industry; and
- improve the technical means, forms and methods for countering terrorism.

The Basic Principles should ensure the strategic national priorities: to improve the quality of life; achieve economic growth; develop fundamental science, education and culture; and ensure national defence and security. The priority directions in the development of science, technology and engineering of federal importance, lists of critical technologies of federal importance (see Appendix 1), and task-oriented programmes of scientific research and experimental development were established to ensure the implementation of the most important innovative projects of state value. This resulted in the goal-oriented federal targeted programme entitled 'R&D in the Priority Directions for the Development of the Scientific–Technological Complex of Russia 2007–2012'. 164

Russian Federation (2002) 'Basic Principles of the Russian Federation Policy on the Development of Science and Technology for the Period to 2010 and Beyond', Approved by the President of the Russian Federation, Vladimir Putin, Moscow, 2002, in Glenn E. Schweitzer and Rita S. Guenther (eds) (2005) Innovating for Profit in Russia: Summary of a workshop (2005), for the Committee on Innovating for Profit in Russia: Encouraging a Market Pull Approach, Office for Central Europe and Eurasia, National Research Council, Russian Academy of Sciences, by Development, Security, and Cooperation (DSC) National Academies of Sciences (NAS), Washington, D.C.

¹⁶³ Ibid.

Ministry of Education and Science of the Russian Federation (2009) R&D in the Priority Directions for the Development of the Scientific–Technological Complex of Russia 2007–2012,

The programme was divided into five blocks: generation of knowledge, development of technologies, technology commercialization, the institutional framework for research and development, and the power infrastructure innovation system. The goal was accelerated development of scientific and technological capacities in priority areas of science, technology and engineering in Russia in accordance with the list of critical technologies of Russia. The programme focused on conducting and funding exploratory research. It directed resources to applied research to those technological areas that were priorities for Russia's economy and could enhance its competitiveness. In addition, the programme funded the creation and support of innovation infrastructure to bridge the gap between R&D and the development of marketable products. There were five priority areas for funding, of which one was the life sciences. In the list of critical technologies that was part of the programme, six dealt directly with biotechnology (see Appendix 1). The programme stated that when developing new technologies co-financing from the private sector must represent around 20-30 per cent of the total cost and if the aim was commercialization it should be 50–70 per cent. 165 Total financing for the programme was 194.9 billion roubles, including expenditure from the federal budget of 133.8 billion roubles. The budget for the programme in 2007 was 11.7 billion roubles (life sciences 2.8 billion roubles), of which capital investment represented 600 million roubles (life sciences 150 million roubles), and R&D 11.1 billion roubles (life sciences 2.7 million roubles). 166 The planned annual budget increases for the programme are shown in Figure 2.

on the Internet: http://fcp.vpk.ru/ext/228/content.htm (retrieved 13 March 2009). The Federal Target Programme is the sum of the activities, procedures and regulations through which the state carries out scientific—technical policy, placing government orders for research and development in the fields of science and technology that are identified as priorities.

¹⁶⁵ Ivanova et al. (2007) *INNO-Policy TrendChart*.

Ministry of Education and Science of the Russian Federation (2009) R&D in the Priority Directions, Appendix 3 and 6, on the Internet: http://fcp.vpk.ru/ext/228/content.htm (retrieved 13 March 2009).

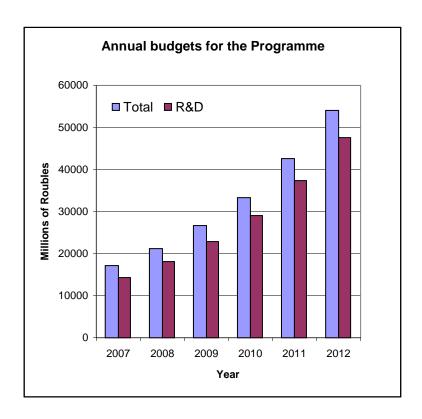


Figure 2. Annual Budget for the programme 'R&D in the Priority Directions for the Development of the Scientific–Technological Complex of Russia 2007–2012', Appendix 5 (figure prepared by K. Westerdahl, FOI, 2007).

One of the major problems in Russia was new companies' difficulties in getting access to capital. The venture capital sector was still poorly developed. Investment in R&D by Russian businesses was very low compared to that of Western companies, and this lack of commitment from the business sector was a weak point of the Russian innovation system. A step in the right direction was taken in 2006 with the establishment of the Russian Venture Company, a state joint stock company (JSC), which was considered to be a positive development towards meeting market requirements and was to prioritize investments in biotechnology and medical technology. It would create investment funds that could finance high-tech and high-risk projects in biotechnology. ¹⁶⁷ A second

¹⁶⁷ Leonov, A. and A. Konov (2007) 'Company Profile, Bioprocess Group LLC: A private biopharmaceutical company in Russia – prospects of development', *Journal of Biotechnology*, Vol. 2, pp. 785-87; and Louët, S. (2005) 'Dmitriy Morosov', *Nature Biotechnology*, Vol. 23, No. 12, on the Internet: http://www.nptemp.ru/files/photo/prod1_docs/227.pdf (retrieved 7 May 2007).

venture capital fund, Bioprocess Capital Partners Management Company, was established as part of the JSC. Approximately 50 per cent of the fund would be invested in biotechnologies and one-third of the fund will be injected into fine chemicals and telecommunications.

Reforming and streamlining the research sector to make it more dynamic and more responsive to innovation was crucial. One positive feature was that R&D expenditure had increased by around 15 per cent in real terms annually since 2003. There was a steady increase in civilian R&D federal funding of \$0.94 billion in 2002 to \$4.51 in 2008. He Much of this had gone into federal goal-oriented programmes. Furthermore, a number of techno-parks had been established. There was a weakness when it comes to monitoring and evaluation of the innovation system's performance. There was, however, a Presidential Council for Science and High Technologies which advised the president on science, technology and innovation policies.

The state budget was the principal source of funding for R&D (62 per cent in 2005¹⁶⁹) and there were four agencies that controlled the civil state R&D budget: the Russian Academy of Sciences (RAS), the Russian Space Agency (Roskosmos), the Federal Agency of Industry, and the Federal Agency of Science and Innovation. There were three funds, the Russian Foundation for Basic Research (RFBR), the Russian Foundation for Humanities (RFH) and the Foundation for Assistance to Small Innovative Enterprises (FASIE). To this should be added that some ministries control funding for R&D. The Ministry of Defence has a large defence-related budget for R&D. It is worth noting that the Ministry of Defence did not take part in the formulation of the Innovation Policy and was keeping its separate status for R&D. The Ministry of Industry and Energy also controls funding for defence-related R&D. The role of the militaryindustrial complex in innovation was not conducive to the growth of private companies or foreign investors. In the development plan until 2020 which was approved by the government in 2009, the state continued to give priority to the military-industrial complex in its high-tech programmes and technological development projects. 170 It can be noted that 73 per cent of organizations carrying out R&D were state owned. A high percentage 77 per cent of researchers work for state owned R&D organizations. ¹⁷¹ It has not been possible in this study to assess the details of the role the Ministry of Defence played in setting the priorities for future R&D funding. The first list of critical technologies

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Dezhina, Irina (2008) Russian Science Policy in Post-Soviet Period, Institute for World Ecobony and International Relations, RAS, Presentation, on the internet: http://www.globelicsacademy.net/2008/2008_prof presentations/GA08%20Lecture%207.pps#25

^{6 (}retrieved 20 March 2010).

Yegerov, Igor (2009) 'Post-Soviet Science', pp. 600-9.

¹⁷⁰ BOFIT Weekly (2009) 'Government Approves 2020 Development Plan', BOFIT Weekly, 23 January.

Dezhina, Irina (2008) Russian Science Policy'.

came in 1996 and included 70 critical technologies; the list in 2002 included 52 critical technologies of which nine were related to biotechnology, and the list from 2006 included only 34 critical technologies where 14 related to biotechnology (Appendix 1) The number of technologies was reduced as they were criticized for being too much like copies of corresponding Western lists. 172

President Medvedev has pointed out in connection with measures needed to support a domestic pharmaceuticals industry that:

This requires us to establish effective mechanisms for supporting them (the industry), and also for attracting to Russia Russian and foreign scientists of repute, and entrepreneurs with experience in commercialising new developments. This is a complex business. We should simplify the rules for recognising degrees and diplomas awarded by the world's leading universities, and also the rules for hiring the foreign specialists we need. ... I am instructing the Government to expand the system of grants on the basis of tenders for those developing new technology. ... University-based business incubators would give graduates the chance to learn how to turn their scientific ideas into profitable business projects. I think this kind of idea deserves our full support. I stress that not only the state but also our major companies should play their part by placing advance orders for the results of the research carried out. You could say this is all part of their social responsibility. A large share of projects should go through an international expert evaluation and be carried out in partnership with foreign centres and companies. 173

If these proposals are carried through, it could make a difference for cutting-edge research in this area in Russia. This shows that the political leadership is well aware of the problems of the Russian innovation system. It is, however, too early to be able to evaluate if these proposals will be implemented and funded.

There was also the new Federal Targeted Programme Scientific and Scientific-Pedagogical Human Resources for Innovation in Russia 2009–2013, which was approved by the Russian Government in June 2008. This would provide incentives for young Russians to go into and to remain in science, education and high technology. Overall, 90.5 billion roubles were planned for the implementation of the programme in 2009–2013, including 80.4 billion roubles from the state federal budget. Among other things, the programme aimed to establish a system which would enhance the inflow of young researchers into science, education and high technology, support the rejuvenation of S&T and

¹⁷³ Presidential Address to the Federal Assembly of the Russian Federation (2009), The Kremlin, Moscow, 12 November 2009, on the Internet:
http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009).

¹⁷² President of the Russian Federation, Decree, No. 842, 21 May 2006.

teaching staff by decreasing the average age of researchers and lecturers to 30–39 years, and boost the number of scientific and educational entities applying advanced international practices. 174

National programmes are the technological base of the country's economy rather than that of an individual industry or region. The Nature of national programmes is scientific as opposed to the production character of federal programmes. National programmes are long-term as a rule 25-30 years while federal federal programmes are medium-term covering 5-10 years. National programmes are controlled by the government and federal programmes by ministries. National programmes imply a transition to a qualitative new level and an increase in the competitiveness of the whole economy rather than that of individual trends in technology as in federal programmes. National programmes are thus fundamentally different from federal programmes.

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¹⁷⁴ European Biotechnology News (2009) 'European – Russian Cooperation to Produce Novel Animal Vaccines from Plants', *European Biotechnology News*, 4 February 2009.

7 Developments in Russian Applied Biotechnology Research

In 2008 the Russian national R&D priorities included critical biotechnologies such as biocatalysts, biosensors, bioinformatics, cell culture techniques, stem cell research, biomedical techniques, and post-genomic research (see Appendix 1). Research funding on the national level for biotechnology was small by international comparison at around \$0.04 billion per year. In 2009, Russia ranked only as the 70th in the world in the biotechnology area. In an optimistic assessment in 2009, by 2010 Russia would be supplying 0.25 per cent of world biotechnology products (in 1990 it was 5 per cent). A total of about 1000 institutions were involved in biotechnology in Russia in 2009 and many focused on the diagnosis and treatment of and protection against infectious diseases (for examples of research carried out at leading institutes see Appendix 3). Table 4 compares 20 countries based on citations in the biotechnology scientific literature and share of world biotechnology patents in 2006. Russia ranks as 17th and 18th, respectively. It can be noted that Sweden ranks as 12th and 13th respectively.

In 2007, Russia was one of the leading producers of immunobiological medication, veterinary products, and environmental protection technology, among other things. Analytical instrument-making was also an expanding field in 2009 and there was an increasing demand for Russian cell technologies, bioinformatics, post-genome technologies (proteomics) and nanotechnologies. ¹⁷⁸

¹⁷⁵ Russian Federation (2008) List of Critical Technologies Approved by Order of the Russian Federation Government, No. 1243, 25 August.

Morozov, Oleg and Raif Vasilov (2008) Rossiiskaia Gazeta, Federal issue No. 4572 (25 January 2008), on the Internet: http://www.eurasiabio.org/media/news/page-4/ (retrieved 10 March 2010). Article by Oleg Morozov (first deputy chairman of the Russian State Duma, and chairman of the Board of Trustees of the Yu. A. Ovchynnikov Russian Society of Biotechnologists), and Professor Raif Vasilov, president of the Russian Society of Biotechnologists. The article raises the most pressing issues of the state of the art of Russian biotechnology, makes a comprehensive assessment and outlines the prospects for the development of the bioeconomy in Russia.

Rabinovich (2007b) 'Biotech in Russia', pp. 778-84; and *Biological Science and Biotechnology in Russia* (2006), Appendix J, 'Selected Research and Related Institutions with Activities Relevant to Infectious Diseases, Diagnostics, Treatment, Prevention, and Control' (Washington, DC, National Academies Press) pp. 115-19.

¹⁷⁸ Rabinovich (2007b) 'Biotech in Russia', p. 778.

Table 4. World Biotechnology Scientific Competitiveness Indicators in 2006 ¹⁷⁹				
Country	Scientific Paper Citations	Rank	Share of Global BiotechnologyPatents (%)	Rank
U.S.	37,822	1	43.3%	1
U.K.	7,565	2	5.3%	4
Germany	7,497	3	9.6%	3
Japan	6,298	4	14.1%	2
France	5,172	5	3.6%	5
Canada	4,194	6	2.7%	6
Italy	3,363	7	1.0%	15
Netherlands	2,665	8	1.7%	9
Australia	2,273	9	2.1%	7
Switzerland	2,168	10	1.4%	12
Spain	2,042	11	0.8%	16
Sweden	1,960	12	1.2%	13
China	1,481	13	1.7%	9
Belgium	1,206	14	1.1%	14
Denmark	1,052	15	1.8%	8
Israel	1,039	16	1.6%	11
Russia	1,019	17	0.2%	19
Finland	893	18	0.5%	18
Korea	841	19	-	-
India	789	20	0.8%	16

In the case of biosensor research, a review of the last ten years of Russian research published in 2004 stated that most techniques had been studied but no dramatic breakthroughs reported and there were few examples of commercial successful applications in Russia. In the case of immune-based products there were a total of 40 companies with around 500 products to a total sales value of \$200 million per year. Research was also being carried out on new types of monoclonal antibodies that could be used in the development of therapeutic

¹⁷⁹ Rosen, Michael (2007) 'The State of Global Biotech: An Ernst & Young perspective', 5 June, on the Internet: http://wistechnology.com/articles/3972/ (retrieved 10 December 2009).

Pisarev, V. V. (2004) [Does Russia Have a Chance of Applying Its Modern Biotech Achievements in the Medical Industry?] (in Russian), *Remedium*, Vol. 4, pp. 29-33.

drugs. 181 Furthermore, there was a Federal Task Programme on Biocatalytic, Biosynthetic and Biosensor Technologies for 2007-2012. Research focused on biosensors for identification of microorganisms based on enzyme biosensors targeting bacterial antigens, as well as tests for toxic compounds, was being carried out at the State Research Centre for Applied Microbiology in Obolensk, the Centre for Toxicology Biopreparations in Serpukhov and Kazan University. The State Research Centre of Biological Instrument-Making was developing optical biosensors for detecting microorganisms. The Bakh Institute of Biochemistry immuno-biosensors was in the process of developing electrochemical enzyme biosensors for detecting toxic compounds as well as optical biosensors for fluorescent ultra amino analysis with simultaneous identification of biological agents and chemical compounds. 182

In Russia stem cell therapy technology was not as developed as it could have been in 2009. This was due to the weak regulatory environment and the inadequate levels of investment. The market volume of stem cell therapies in Russia was much smaller than in the United States and in Europe. Human and animal stem cell transplants were being done in a select number of Russian clinics and medical centres.

Efforts to exploit biotechnology for the agricultural sector were not consistent and involved relatively small sums devoted to R&D. This also applied to genetically modified crops. A few experimental trials were being carried out but a costly and time-consuming process is usually involved before general use can be allowed for commercial cultivation. In the area of transgenic animals and plants, Russian R&D remained competitive in an international perspective. As of 2007 there were no commercial transgenic products in Russia and this was an area where Russian biotech could become a world leader. 183 There were GM (genetically modified) crops, such as soybean, maize, rice and sugar beet, approved for use in food in Russia. 184 Several Russian agencies and local administrations were trying to declare all of Russia a 'GMO-free zone' and Moscow Mayor Yurii Luzhkov supported the Moscow city government taking this direction. Mayor Luzhkov and some governors of other Russian territories hope to place a moratorium on biotech products throughout Russia. 185

¹⁸¹ Ivanov, Pavel K. et al. (2007) 'Atemonate and Imuteran: Novel Russian monoclonal antibodybased therapeutic agents', Journal of Biotechnology, Vol. 2, pp. 863-70.

Reshetilov, Anatoly N. (2007) 'Biosensor Development in Russia', Journal of Biotechnology, Vol. 2, pp. 849-62.

Adam, D. (2007) 'Down on the Pharm', *The Guardian*, 30 April, on the Internet: http://www.guardian.co.uk/science/story/0,,2068736,00.html (retrieved 8 May 2007).

Vassilieva, Yelena and Cynthia Barmore (2008) Russian Federation Biotechnology Annual 2008, GAIN Report, No. RS8056, U. S. Department of Agriculture (USDA) Foreign Agriculture Service, 24 July 2008, on the Internet: http://www.fas.usda.gov/gainfiles/200807/146295243.pdf (retrieved 10 March 2010) ¹⁸⁵ Ibid.

Research concerning the beneficial plant-microbe interactions has developed rapidly, dealing with improving nutrition or enhancing protection of plants using genetic engineering methods. This included mycorrhizal symbiosis or nitrogenfixing symbiosis and so on. ¹⁸⁶ In October 2009, in special fields in the Leningrad and Novgorod regions, there were plans to plant about 300 000 seedlings of transgenic forms of aspens and birches. Russia's scientists were studying genetically modified plants, mainly in greenhouse conditions. Russia has a legislative ban on the widespread introduction of transgenic plants, but studies were allowed just prior to field trials. In 2007, it was expected that amendments would be proposed to the 1992 law on genetic engineering in order to lift the present ban. There was also progress in developing the system for evaluating risks of GM (genetically modified) foods and to control their distribution. ¹⁸⁷

One of the positive outcomes of the proposal for a union between Russia and Belarus was a project developing transgenic goats producing lactoferrin. The budget for this was 50 million roubles, Russia financing 65 per cent and Belarus the remainder. The first phase was finished in 2006 and the joint company BelRosTransgen obtained the first offspring in the same year; the project was scheduled to continue in 2007–2010. Russian scientists have developed sheep that produce spider silk protein in their milk. Spider silk is a very strong material with potential uses for uniforms and bullet-proof clothing, optical fibres, biodegradable sutures, artificial tendons and ligaments, ropes, parachutes and so on. Transgenic plants have also been developed in Russia carrying the spider silk gene. A Canadian company has developed the same transgenic model for spider silk as the Russian scientists in cooperation with the U.S. Army and obtained a worldwide patent for this innovation, which could prevent the Russian scientists from commercializing their research. There are also many U.S. and European

¹⁸⁶ Tikhonovich, Igor A. and Nikolai A. Povorov (2007) 'Cooperation of Plants and Microorganisms: Getting closer to the genetic construction of sustainable agro-systems', *Journal of Biotechnology*, Vol. 2, pp. 833-48

of Biotechnology, Vol. 2, pp. 833-48.

187 Tyshko, Nadezhda V., Irina N. Aksyuk and Victor A. Tutelyan (2007) 'Safety Assessment of Genetically Modified Organisms of Plant Origin in the Russian Federation', *Journal of Biotechnology*, Vol. 2, pp. 826-32.

Borodin, Pavel (2006) 'Even Grander Tasks and Projects Ahead', Rossiiskaia Gazeta, 27 December; on the Internet: http://www.rg.ru/2006/12/27/borodin.html (retrieved 5 January 2007).

¹⁸⁹ Mednovosti (2006) 'First Transgenic Goats Born in Belorussia', *Mednovosti*, 2006, on the Internet: http://medportal.ru/mednovosti/news/2006/04/10/trans/ (retrieved 24 April 2006); and Rosbalt (2006) 'Scientists of Belarus will Continue Experiment on Breeding Transgenic Goats', *Rosbalt*, on the Internet: http://www.rosbalt.ru/2006/11/22/275999.html (retrieved 7 May 2007).

¹⁹⁰ Kuzina, O. (2006) 'Poslednie nauchnye razrabotki v sfere sel'skogo khozyastva – predstavili v Moskve' [Latest Scientific Development in Sphere of Agriculture Presented in Moscow], Pervyi Kanal television, 16 February, on the Internet:

http://www.ltv.ru/owa/win/ort6_main.main?p_news_title_id=86141&p_news_razdel_id=4 (retrieved 23 February 2006).

Lazaris, Anthoula et al. (2002) 'Spider Silk Fibers Spun from Soluble Recombinant Silk Produced in Mammalian Cells, *Science*, Vol. 295, No. 5554, pp. 472-76, on the Internet:

patents for isolation and uses of lactoferrin, but apparently none filed by Russian researchers. 192

President Medvedev has stated that Russia's planned version of Silicon Valley would be built in the Moscow region town of Skolkovo, near existing technoparks. The new town will have five priorities for modernization: energy, IT, telecommunications, biotechnology and nuclear technology. Work on the project would begin 2010 and be financed in part by the government with \$340 million from the modernization and innovation budget. The Russian billionaire Viktor Vekselberg has been appointed as chairman of the Russian section of a council responsible for overseeing the Skolkovo innovation centre. The centre was to be built near a business school instead of locating it near research centres. This is not the first time the Russian government has tried to create high-tech centres for innovation to attract engineers and scientists. Four special economic zones in St. Petersburg, Tomsk, Dubna and Zelenograd have all been called new centres for research and development in the fields of biotechnology, nanotechnology, information technology, nuclear technology and telecommunications. ¹⁹³

Nanotechnology has been given high priority among the Russian R&D programmes. ¹⁹⁴ Two organizations – the FMBA (the Federal Medical-Biological Agency) and RUSNANO (the Russian Corporation for Nanotechnologies) – have agreed to cooperate on applied uses of nanobiotechnology in medicine and pharmacology. ¹⁹⁵ In 2008 a Supercomputer Cluster Center, the Center of Competence in Biotechnology, Aerobiology, Bionanotechnologies, General and Industrial Microbiology, was set up at Vyatka State University. ¹⁹⁶ A National Doctrine of Nanotechnology Development was adopted. In this national doctrine,

http://www.sciencemag.org/cgi/content/abstract/sci;295/5554/472 (retrieved 7 May 2007); and Space Daily (2002) 'Spinning a Tough but Silky Yarn', *Space Daily*, 22 January, on the Internet: http://www.spacedaily.com/news/materials-02a.html (retrieved 7 may 2007).

http://www.spacedaily.com/news/materials-02a.html (retrieved 7 may 2007).

192 A search for 'lactoferrin' on the Internet: http://www.freepatentsonline.com (retrieved 9 May 2007) resulted in 3464 hits. Of U.S. patents and patent applications and European patents, 160 had the word 'lactoferrin' in the title. The search for 'lactoferrin' in title and Russia as the assignee country resulted in no hits (search by Westerdahl online, 9 May 2007).

Moscow Times (2010) 'Skolkovo Designated Silicon Valley Location', *The Moscow Times*, 19 March 2010, on the internet: http://www.themoscowtimes.com/business/article/skolkovo-designated-silicon-valley-location/402114.html (retrieved 7 April 2010)

194 Ministry of Fiberation (2027) (1977)

Ministry of Education and Science (2007) 'The Interdepartmental Working Group Has Considered the Modified Project of the Program of Development of the Nano-industry in the Russian Federation till 2015', Press release, on the Internet: http://www.mon.gov.ru/news/press/3596/ (retrieved 31 March 2007).

¹⁹⁵ RUSNANO (2010) 'RUSNANO and the Federal Medical-Biological Agency Sign Cooperation Agreement', RUSNANO, on the Internet: http://www.nanotech-now.com/news.cgi?story_id=36776 (retrieved 15 February 2010) and in Russian on the Internet: http://www.rg.ru/printable/2010/02/16/nano.html (retrieved 15 February 2010).

¹⁹⁶ EuroasiaBio (2008) 'Supercomputer with Basic Specialization in Bio- and Nanotechnologies', EuroasiaBio, 15 February 2008, on the Internet: http://www.eurasiabio.org/media/news/page-4/ (retrieved 10 March 2010).

a special section was devoted to nanobiotechnology and nano-medicine. This included nano-chips for diagnosis of infectious diseases (hepatitis, tuberculosis and HIV/AIDS) and identification of toxins, molecular devices for sequencing, self-replicating genomes for the production and screening of new drugs and biocompatible biomaterials. Thirty institutes and companies were involved in the programme. For the period 2008–2010, Russia planned to invest \$11 billion in nanotechnology; 90 per cent was earmarked for civilian applications and 10 per cent for defence applications. The following research priorities were listed: 199

- nano-chips for diagnostics of somatic and infectious diseases;
- a new generation of pharmaceuticals based on nano-particles for drug delivery;
- medical nano-robots for nano-surgery;
- use of inorganic nano-pores for molecular devices for genome sequencing;
- self-reproducing genomes for production and screening of new drugs as well as modelling of pathological processes; and
- biocompatible nano-materials, for example for artificial organs.

Nano-diagnostic devices were to be developed using different principles such as laser, biosensors or PCR (polymerase chain reaction) for diagnostics in oncology, for endocrine and cardiovascular diseases and for viral or bacterial infections. Nano-diagnostics would also be used for the evaluation of drug resistance of different infectious strains, for example, those causing tuberculosis.²⁰⁰

¹⁹⁷ Rabinovich (2007b) 'Biotech in Russia', pp. 778-84.

¹⁹⁸ Schiermeier, Quirin (2009) 'High Hopes for Russia's Nanotech Firms, but an Ambitious Government Initiative has been Slow to Incubate a Domestic High-tech Industry', *Nature*, No. 461, pp. 1036-39; and Business Week (2007) 'Russia to Invest \$1B in Nanotechnology', *Business Week On-line*, on the Internet: http://www.businessweek.com/ap/financialnews/D8OJ4NS80.htm (retrieved 18 April 2007).

¹⁹⁹ Rabinovitch, Mikhail (2007) 'Prospects of Nanobiotechnology and Nanomedicine in Russia', Journal of Biotechnology, Vol. 2, pp. 788-89.

Leading institutes in this area were: Research institute of Biomedical Chemistry (RAMS); Institute of Molecular Biology (RAS); Centre of Molecular Diagnostics; Institute of Bioorganic Chemistry (RAS); Physico-Technical Institute (RAS); Physico-Chemico Medicine (MOH); Institute of Virology A/S NT-MDT; Centre of Bioengineering (RAS); MTC (SibRAS); Centroida Ltd; A/S Russian Electronics; Institute of semiconductor physics (SibRAS); and Schools of Physics and Chemistry at Moscow and Novosibirsk universities.

8 The Russian Biotechnology Market

In recent years Russia has experienced rapid economic growth, which averaged 6.7 per cent over the last five years. GDP increased by 82 per cent between 1999 and 2008 in real terms, helped by a steady increase in oil prices from the low of \$9 per barrel of Urals brand in early 1999 to the peak of \$138 per barrel in August 2008. The Russian economy was then severely affected by the 2008–2009 global financial crises through a steep reduction in commodity prices, capital flow reversal and the credit crunch, and lower global demand for Russian manufactured goods. Russia is heavily dependent on exports of raw materials, oil and gas, together with strategic metals and timber, which emphasizes the economy's instability as its export earnings depend heavily on changes in oil prices. From 2002 to 2007 the price of oil increased, but in the later part of 2008 it dropped dramatically and remained on a lower level for much of 2009.

This strong economic growth, coupled with several government initiatives, benefited the biotechnology area as well. In 2015–2020 the Russian Federation should, according to its long-term planning, be among the five leading economies in terms of GDP.²⁰³ In the 2008 edition of the *World Competitiveness Yearbook*, published by the IMD (International Institute for Management Development), Russia is still ranked close to the bottom of the league table, as number 47 (in 2007 it was number 43), just above Romania, out of 55 countries surveyed.²⁰⁴ The trend confirms the image of a country that shows growth without development and that has significant difficulty in reducing its dependence on raw materials.²⁰⁵ Foreign investments decreased by 41 per cent in 2009. There seems to be a lack of viable strategies to lead the country into a post-industrial world. This will inevitably have negative effects: in the foreseeable

²⁰¹ EBRD (2009) 'Strategy for the Russian Federation 2009–2012', European Bank for Reconstruction and Development, on the Internet:

http://www.ebrd.com/about/strategy/country/russia/strategy.pdf (retrieved 5 March 2010).

202 Leijonhielm et al. (2009) 'HIV/AIDS – ett underskattat problem' [HIV/AIDS: An underestimated problem] in *Rysk militär förmåga i ett tioårsperspektiv: ambitioner och utmaningar 2008*[Russian Military Capacity in a Ten-year Perspective: Ambitions and challenges 2008], Report FOI-R--2707--SE (Stockholm, FOI), pp. 110-111.

²⁰³ Ministry of Economic Development and Trade (MEDT) (2008) Concept for Long-term Socio-economic Development of the Russian Federation until 2020, Approved by the Russian Government, V. V. Putin, 25 November 2008; and Oxenstierna, Susanne (2009) Russia in Perspective, Scenarios of Russia's economic future 10 to 20 years ahead, Report FOI-R--2774--SE (Stockholm, FOI).

World Competitiveness Scoreboard (2008), on the Internet: http://www.biorosinfo.ru/biotechnologia/Grafik_konkurent_2008.pdf (retrieved 17 December 2009).

The IMD World Competitiveness Yearbook, on the Internet:
http://www.imd.ch/research/publications/wcy/wcy_book.cfm (retrieved 21 May 2007); and Leijonhielm et al. (2009) 'HIV/AIDS – ett underskattat problem', pp. 110-11.

future Russia will not be able to maintain economic growth and will be competitive on the world market only in terms of raw materials and a few high-tech products. ²⁰⁶ President Medvedev pointed out in 2009 that:

We must begin the modernisation and technological upgrading of our entire industrial sector. I see this as a question of our country's survival in the modern world... These are the key tasks for placing Russia on a new technological level and making it a global leader. These priorities include introducing the latest medical, energy and information technology, developing space and telecommunications systems, and radically increasing energy efficiency.²⁰⁷

In another interview he underlined that:

Modernisation, we are keen to make sure that it takes place as quickly as possible. Not a year, not two, not three, but maybe 10–15 years – that is a perfectly plausible time frame in which to create a new economy, an economy that will be competitive with other major world economies. ²⁰⁸

During 2009, the Russian economy suffered from the world economic crisis and there were estimates that it would shrink by around 8–9 per cent in 2009.²⁰⁹ According to Medvedev, GDP would fall by 7.5 per cent for 2009 due to the economic crisis.²¹⁰ It was very difficult to predict how Russia's economy would develop over a longer period. Some analysts believed that GDP growth would be limited to around 1 per cent in a long-term perspective.²¹¹

It was also expected that foreign investment in Russia would continue to decline. This is a result of stringent new laws on foreign investment reserving the really important sectors for the state. There was still no sign that the state would move towards the genuine rule of law, despite President Medvedev's statements on the subject, or that key state actors would voluntarily relinquish their ownership of

November 2009).

²¹⁰ Presidential Address to the Federal Assembly of the Russian Federation (2009) The Kremlin, Moscow, 12 November.

²⁰⁶ Leijonhielm et al. (2009) 'HIV/AIDS – ett underskattat problem', p. 136.

²⁰⁷ Presidential Address to the Federal Assembly of the Russian Federation (2009), The Kremlin, Moscow, 12 November 2009, on the Internet: http://eng.kremlin.ru/speeches/2009/09/10/1534 type104017_221527.shtml (retrieved 19

²⁰⁸ Kleimenov, Kirill (2009) 'Conversation with Dmitry Medvedev. Answers to questions from director of News Programmes at Russia's Channel One Kleimenov', 11 October 2009, on the Internet: http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009).

²⁰⁹ Russia Pharmaceuticals & Healthcare Report 2008, Business Monitor International, on the Internet: http://www.businessmonitor.com/pharma/russia.html (retrieved 26 February 2008).

Rosefielde, Steven, Professor (2009) Personal communication, November.

key firms and sectors. Indeed, the state was apparently moving to expand its holdings, particularly in the energy, defence, and high-tech sectors. ²¹²

Before the crisis, growth in biotechnology on the world market was estimated at 7–9 per cent annually. In the world biotechnology market 2004 for biopharmaceutical products accounted for 17 per cent, food and agriculture for 28 per cent, enzymes and preparations for detergents for 13 per cent and the production of modified plants for 18 per cent. In value terms, the medical or health care segment generated 69.4 per cent of the market value. The world market for biopharmaceutical products was estimated for 2005 to be \$59.5 billion with an annual growth rate of 15–33 per cent. A doubling of the market was expected by 2011. In accordance with the colour classification for biotechnology trends, more than 60 per cent of world production is accounted for by the 'red' biotechnology (biopharmaceuticals and biomedicine), 12 per cent by 'green' (agro-food products) and the rest by 'white' biotechnology (biomaterials).

²¹² Blank, Stephen (2008) 'Foreign Investment in Russia Will Continue to Decline', 3 July, on the Internet: http://www.glgroup.com/News/Foreign-Investment-in-Russia-Will-Continue-to-Decline-Stephen-Blank-US-Army-War-College-24905.html (retrieved 24 November 2009).

Abercade Consulting (2004) 'Biotechnology: Review of the market in 2004', Report, on the Internet: http://www.abercade (retrieved 31 January 2008); and Farmatsevticheskii Vestnik (2006) 'Is the Commercialisation of Russian Biotechnology Products? The question remains open' Farmatsevticheskii Vestnik, 28 February.

open' *Farmatsevticheskii Vestnik*, 28 February.

214 Abercade Consulting (2004) 'Biotechnology: Review of the market'; and 'Bacteria That Have a Billion', on the Internet: http://www.rusbiotech.ru (retrieved 2 March 2009).

Reuters (2009) 'Research and Markets Biotechnology: Global industry guide provides expert analysis on a global, regional and country basis', 18 February, 2009, on the Internet: http://www.reuters.com/article/pressRelease/idUS202223+18-Feb-2009+BW20090218 (retrieved 23 February 2009).

²¹⁶ Bairamashvili and Rabinovich (2007) 'Russia through the Prism', pp. 801-17.

Parliamentary hearings (2009) Working Papers for Development of the Strategy for the Biotechnology Industry until 2020 prepared for the Parliamentary hearings on 15 October 2009 by experts from the company Advanced Research (St Petersburg, on the Internet: http://www.aresearch.ru) commissioned by the all-Russia public organization the Russian Society of Biotechnologists in Russia, on the Internet: http://biorosinfo.ru/ (retrieved 16 December 2009).

In 2004–2009, Russia's share of the world biotechnology market was less than 0.2–0.8 per cent. It was expected that in 2010 the Russian share of the world market for biotechnology products would be 0.3 per cent (compared with 42 per cent for the U.S., 22 per cent for the EU countries, 10 per cent for China and 2 per cent for India). Twenty-five years ago, Russia's share was 5 per cent.²¹⁸

Table 5. The Russian Production/Market in Biotechnology Compared to Global Production/Market, in U.S. \$ (millions) (compilation of information from several sources)²¹⁹

Year	World	Russian Production	
1980	30	1.5	
1990	95	3.2	
2001		1.4	
2002	163		
2005		1.6	
2007	172	1.6	
2010		1.6	
2012	276		

Table 5 compares Russian biotechnology production with the world market since 1980, and shows that there has been no increase, in contrast to what has happened worldwide. In Russia the government spends only \$0.04 billion a year in 2005 on the biotechnology area, compared to \$1 billion in China and more than \$10 billion annually in the U.S. and the EU countries. There is also a risk in having only a limited number of private companies investing in biotechnology innovations: in Russia private companies only account for 30 per cent of investment. In the U.S. the share is 60 per cent and in the EU area it is 50 per cent. Such a high degree of state involvement in Russia increases the risks to

²¹⁸ Parliamentary hearings (2009) Working Papers for Development of the Strategy for the Biotechnology Industry.

World of Science (2004) 'How to Overcome Crisis', In the World of Science, No. 12 (December); Vasilov, R. (2006) 'Russian Society of Biotechnologists', St Petersburg, Presentation at a conference, 2006, on the Internet: http://www.biorosinfo.ru (retrieved 20 October 2007); Abercade Consulting, 'Biotechnology: Review of the market in 2004'; 'Bacteria That Have a Billion'; 'New Concept of Partnering on Biotech Resources – Report from Biotechnica 2008', Hanover, 24 October 2008, on the Internet:

http://info.hktdc.com/imn/08102404/trade069.htm (retrieved 20 March 2009); and Reuters (2009) 'Research and Markets: Biotechnology'.

investors due to widespread corruption.²²⁰ The Russian market grew by around 33 per cent in 2005, 20 per cent in 2006 and 10.5 per cent in 2007, and growth was projected to stabilize at around 10 per cent for the period 2008–2010.²

According to the Ministry of Education and Science, the Russian biotech market in 2010 was estimated to be \$4.4 billion, of which \$1.8 billion would be domestically produced.²²² Approximately three-quarters of the Russian biotech market consisted of imported products.²²³ Foreign biotechnology preparations for animal husbandry accounted for 95 per cent and for the arable sector 75 per cent of the Russian market. The Russian biotechnology market in 2007 was divided into biopharmaceuticals (64 per cent), agriculture (20 per cent), yeast (9 per cent), enzymes (4 per cent), environmental protection (1 per cent), and live cultures with microorganisms (1 per cent). The share of Russian companies in the domestic biotechnology industry for 2002–2006 was around 25–30 per cent. Investments in biotechnology 2007 increased by 200 per cent compared with 2006²²⁶ and continued to increase in 2008. The growth sectors for Russian biotechnology were pharmaceuticals, dietary supplements, cosmetics, agriculture, food processing, and environmental technology. In 2008 there were around 2000 manufacturers (500 with registered products) in Russia. Private companies in Russia are mainly engaged in the agricultural and pharmaceuticals sectors. The emerging Russian biotech market was particularly strong in the following areas:

- Expression and purification of biologically active molecules and peptides;
- Fermentation at production scale;
- Original in vivo and in vitro methods of modelling a range of neurological disorders;
- State-of-the-art pilot-scale drug manufacturing facilities;
- Plant cell culture scale-up and industrial production;
- Peroral, intranasal and aerosol drug delivery systems;

²²⁰ Liuhto, Kari (2009) 'Russia's Innovation Reform – The current state of special economic zones', Review of International Comparative Management, Vol. 10, Issue 1.

Russia Pharmaceuticals & Healthcare Report.

²²² Rabinovich (2007b) 'Biotech in Russia', pp. 775-7.

²²³ Vasilov (2006) 'Russian Society of Biotechnologists'.

Mezenova, Olga (2008) 'Biotechnology in Russia: Innovation sectors in research and industry', Russian Society of Biotechnologists, Presentation at German Russian Workshop in Biotechnology, Hanover, on the Internet:

http://www.owwz.de/fileadmin/Biotechnologie/BioVeranst/Biotechnica 2008/Mezenova.pdf (retrieved 10 March 2009).

Rabinovich (2007b) 'Biotech in Russia', pp. 775-7.

²²⁶ Ibid., pp. 778-84.

- Preclinical drug screening facilities operating according to GLP (Good Laboratory Practice) standards;
- The SPF (specific pathogen free) laboratory rodent breeding facility; and
- · Next-generation vaccines, immunomodulators, and cytokines.

In the late 1990s, most Russian biotechnology products, especially pharmaceuticals, had been replaced by foreign competitors' products on the Russian market. For example, over the period 1990–2003, production of single cell protein fell from 1 325 000 to 50 000 tonnes and for enzymes production fell from 8 789 000 to 1 560 000 tonnes. Domestic production accounted for 30 per cent of consumption and was dominated by enzymes required for alcohol/beer production and for livestock. In 2008, the size of the market of enzymatic products for agriculture had fallen by 7.5 per cent compared to 2007 and the share of imports of enzymatic products reached 94 per cent in 2007. There is now only one manufacturer of amino acids for animal feed in Russia. The share of imports in the amino acids market, by volume, in 2008 amounted to 73.5 per cent.

Antibiotic production (the sum of all types) fell from 2 420 000 to 195 000 tonnes between 1990 and 2003. Some basic biotechnology products are no longer produced in Russia and there has been a dramatic drop in the domestic production of amino acids, antibiotics and insulin – almost reaching zero. One reason for this is that the industry was not competitive. Another is that the companies lost their state subsidies after the collapse of the Soviet Union, which resulted in major financial difficulties for many of them. The main reasons, however, are the low level of investment in the sector, outdated production equipment and lack of qualified personnel. Table 6 compares domestic biotechnology production with the total market in Russia for biotechnology products, by value, in 2004.

Abercade Consulting (2004) 'Industrial Enzymes in Russia 2004', Report, on the Internet: http://www.abercade.ru (retrieved 31 January 2008).

²²⁷ According to data from GiproNIImedprom, as presented in Vasilov (2006) 'Russian Society of Biotechnologists'.

Abercade Consulting (2009) 'Russia's Market of Amino Acids in 2008', Report, 2009, on the internet: http://www.abercade.ru/en/materials/analytics/6_2009_t19.html (retrieved 10 March 2010)

²³⁰ According to Data from GiproNIImedprom' in Vasilov (2006) 'Russian Society of Biotechnologists'.

Table 6. The Russian Market for Some Biotech Products, 2004 ²³¹			
Product	Total value \$ million	Domestic value \$ million	
Live cultures of			
microorganisms.	5.8	0.1	
Yeast	81.5	64.0	
Oil and mining	5.5		
Livestock industry	178.0	63.0	
Improve agricultural			
cultivation	5.0		
Environmental protection	9.7	8.8	
Biopharmaceuticals	560.0	67.0	
Total biotech production	885.0		

Due to the economic problems following the collapse of the Soviet Union, which resulted in a fragmentation of biotechnology into many small units, spin-offs were often formed from different institutes to earn money. Later there was a trend to merge units into larger units and then into even larger organizations, such as Biomac (founded in 2001), Mikrogen (founded in 2003)²³² and Tempo (established in 2004) (see Appendix 3).²³³ Biomac was formed to coordinate a programme with a focus on biotechnology in medicine and its 60 members cover a broad field.²³⁴ They include investment companies but also Biopreparat RAO. RAO Rosagrobioprom and Vector with defence links. Meanwhile, public-private partnerships were encouraged in a new Russian Government programme which started in 2006. The investments needed were estimated to be \$40.5 billion, focused on biofuels, plant protection and pharmaceuticals.²³⁵

Why did Russia develop these state corporations after having privatized most of its industry in the previous decade? The reason could be that private investors were unwilling to develop these private biotechnology industries, possibly because in 2009 key industries had to be given state support if they were to

²³¹ Abercade Consulting (2004) 'Industrial Enzymes in Russia 2004'.

Mikrogen homepage, on the Internet: http://www.microgen.ru/ (retrieved 7 May 2007).

NP Tempo homepage, on the Internet: http://www.nptemp.ru (retrieved 7 May 2007).

The non-commercial partnership Consortium Biomac, homepage on the Internet:

http://www.biomac.ru (retrieved 8 May 2008).

235 'New Concept of Partnering on Biotech Resources – Report from Biotechnica 2008', Hannover Biotechnica, 24 October 2008, on the Internet: http://info.hktdc.com/imn/08102404/trade069.htm (retrieved 20 February 2009).

survive. What Russia was facing was a form of the 'Dutch Disease'. 236 This could explain why private investors were reluctant to invest outside export sectors; and one clue was probably the exchange rate of the rouble.²³⁷

Many of the biotechnology companies that appeared at the end of the 1990s focused on the area of biopharmaceuticals and they were often subsidiary companies from large research institutes. These focused on, for example, interferons, erythropoietin or granulocyte colony stimulating factor. One reason for this was that key patents were about to expire. At that time most drugs based on recombinant proteins were imported into Russia.²³⁸ There were in 2009 several examples of significant projects in the field of biopharmaceuticals, for example:²³⁹

ZAO Generium (Vladimir Region) focuses on the construction of biotechnology research and is a production facility to produce drugs to treat blood diseases, including investments of 2 billion roubles. It was planned to develop and bring to the market up to ten new biotech drugs annually with expected production by value of 2.7 billion roubles in 2010 and 7.6 billion roubles by 2013.

HIMRAR (Moscow Region) is an incubator for innovative companies involved in developing and providing for the market innovative drugs for the treatment of cardiovascular, oncological and infectious diseases and diseases of the endocrine and central nervous system. The investments were 4.3 billion roubles.

ZAO Biocad (Moscow Region) is a research and production company engaged in the development of original and generic biologics for the treatment of urological, gynaecological, oncological and neurological diseases (for details see Appendix 3).

²³⁶ The Dutch Disease is a concept that explains the apparent relationship between an increase in the exploitation of natural resources and a decline in the manufacturing sector. The theory is that an increase in revenues from natural resources will deindustrialize a nation's economy by raising the exchange rate, which makes the manufacturing sector less competitive and leaves public services entangled with business interests. However, it is extremely difficult to conclude definitively that natural resource exploitation is the primary or sole cause of decreasing revenues in the manufacturing sector, since there are often many other factors at play in the very complex global economy. Wikipedia (2010), on the Internet: http://en.wikipedia.org/wiki/Dutch_disease (retrieved 10 March 2010).

Sapir, Jacques (2009) 'President Medvedev's Vision of Russia's Future – Right on ends, but wrong on means', RIA Novosti, 30 November 2009, on the Internet: http://en.rian.ru/analysis/20091130/157039352.html (retrieved 5 March 2010).

Leonov and Konov (2007) 'Company Profile, Bioprocess', pp. 785-7.

²³⁹ Russian Society of Biotechnologists (2009) [Draft for Strategy for the Development of the Biotechnology Industry in Russia 2010-2020] (in Russian), on the Internet: http://www.biorosinfo.ru/papers-society/Strategy_Bioindustry.pdf (retrieved 16 December 2009).

Bioprocess (Moscow) is a research and production company (group of companies) set up to manufacture biotech substances. The company is engaged in both production of generic drugs and innovative designs. It plans to create up to ten plants for the production of high-tech bio-generics, including an investment cost of 10.8 billion roubles (for more details see Appendix 3).

Since the 1990s, the biotech industry in Russia has suffered from poor structure, obsolete equipment, and the low technological level of its products, which do not meet the requirements of international standards (including GMP), as well as having no experience of Western-type marketing or management. The previous good working relationships between research and production entities had been disrupted or terminated in many cases and there was an increasing distance between the researchers' ideas and transferring them into profitable products. These problems were perhaps not surprising as previously much of the activity had been defence-oriented and centrally controlled.

It has been difficult to commercialize research results in general, not only in the biotech area. Many researchers believed, after the collapse of the Soviet Union, that it was unfortunate that the Russian biotech industry in the first place sought foreign partners instead of exploiting domestic advances in research during the 1990s. It was a particular feature of the Soviet structure that it was strong in some research areas but weak when it came to translating research results into products or exploiting them. It should also be noted that some research that claimed to be done for civilian applications was just a cover for military-oriented research. It was, in other words, perhaps not surprising if there were few civilian products as a result of this research. Gennady Onishchenko, member of the Medical Academy, estimated that in 2004 Russia was lagging at least 15 years after the West in the genetic engineering area. The problems of Russian biotechnology at that time have been described elsewhere.

Since 2005 the Russian Government has realized that biotechnology should be a priority and that both economic and legal conditions must be improved if the industry is to develop. Russian biotech specializes for example in medical applications (genetics, immunology, genetic modification of microorganisms,

²⁴⁰ Greenshields, Rimmington and Rothman (1990) 'Perestroika and Soviet Biotechnology'.

²⁴¹ Rimmington (1995) 'On the Eastern Front: Legacy of biotechnology visionary lives on', *Microbiology Europe*, Vol. 3, No. 3, pp. 14-5.

²⁴² Kommersant (2004) 'Russia 15 Years Behind in Genetics', *Kommersant*, 26 October 2004.
²⁴³ Moshkin, Andrei G. (2003) 'Biotechnology and Business in Russian Federation', in *Proceedings of the First Workshop on Biological Security*, Moscow, 23 October 2003, on the Internet:
http://www.bio.su./old/en.htm#cont (retrieved 24 June 2008); and Evstigneev, Valentin I. (2003) 'The Problems of Biological Safety in Russia', in *Proceedings of the First Workshop on Biological Security*, Moscow, 23 October 2003, on the Internet:
http://www.bio.su./old/en.htm#cont (retrieved 24 June 2008).

plants and animals, cloning and cell transplantation, protein synthesis) and in the agricultural sector, including transgenic plants with altered genotypes. Current trends and promising areas of biotechnology were described in detail in a forecast by the Russian Academy of Sciences on the development of scientific and technological areas with significant potential for application in the long term. After some restructuring of various ministries, the Commission for Genetic Engineering was re-created in 2004 and chaired by the Ministry of Education and Science. The new commission helped to shape government policy regarding genetic engineering and in terms of regulations in the area of genetic engineering and biotechnology. It also ensured a sufficient scientific basis to evaluate the risks of biotechnology.

8.1 Biotechnology one area for industrial espionage

Biotechnology companies in the West were used to being the target for economic and industrial espionage during the 1990s. One reason for this was the very sophisticated techniques that were being developed, the very rapid pace of developments in biotechnology and the high costs involved in many development projects – not least for potential new drugs. The biotech market is highly competitive and new innovations can be extremely valuable. The biotechnology area is knowledge-driven; biotech companies are often dependent on keeping trade secrets from competitors and competition is fierce, so that company secrets are targets for illicit information collecting. There are examples of a wide variety of information being collected which can be seen as theft or alleged theft of trade secrets, such as delivery technologies for small interfering RNA molecules, new treatments for Alzheimer's disease, new immunosuppressant drugs and so on. One report indicate a potential attempted theft of sensitive information at the Virology and Biotechnology Centre Vector in Koltsovo in 2010 but the facts in

²⁴⁴ Parliamentary hearings (2009) Working Papers for Development of the Strategy for the Biotechnology Industry (Appendix 1). Forecast for the long-term scientific and technological development of Russia, developed by Russia Academy of Sciences, in accordance with List of Orders of the President of Russia Dmitry Medvedev from 4 May 2008, No. Pr-861 HS, on the Internet: http://biorosinfo.ru/ (retrieved 16 December 2009).

²⁴⁵ Russian Federation (2005) 'Decree on Creation of the Interagency Commission for Genetic Engineering, No. 154', 27 May 2005.

²⁴⁶ USDA (2005) Russian Federation Biotechnology Annual Agricultural Biotechnology Report 2005, U.S. Department of Agriculture Foreign Agriculture Service, Gain Report, No. R55054, 15 July 2005, on the Internet: http://www.fas.usda.gov/gainfiles/200508/146130616.pdf (retrieved 19 March 2008).

Mollman, Elliott S. (2007) 'The Threat from Within: Trade secret theft by employees', *Nature Biotechnology*, Vol. 25, No. 3, pp. 293-5.

this case are not clear but could point to this potentially growing problem.²⁴⁸ The list is long, and each case was unique due to the type of activity or substance being targeted. In many cases government laboratories or companies were not well protected against this type of illicit activity. There was an instance in Sweden in 2006 when a Russian scientist at the Swedish Agricultural University's Genetic Centre in Uppsala was apprehended by the Swedish Security Police for attempted espionage. He had supplied his Russian contacts with information on the ongoing project in virology and also information on his colleagues in the laboratory where he worked. The scientist was, however, never tried in Sweden.

It has been estimated that U.S. biotech companies lose trade secrets worth millions of dollars each year. 249 In many cases it is their own employees who for different reasons sell information. 250 Foreign intelligence services have also increasingly, since the Cold War, engaged in industrial espionage. One of several most frequently targeted industries in the U.S. appears to be biotechnology.²⁵ There are a number of ways in which trade secrets are stolen, ranging from using disgruntled employees to computer hacking, stealing laptops, and stealing or copying documents.²⁵² It was also well known that many biotech companies would rely on expertise from academic bodies for their research, and they tended to have a different view on publication and information sharing. Using guest scientists was a well known way to gain access to sensitive information. As research in biotechnology has become transnational and global, many nationalities are usually engaged in major research projects, and individuals can be used to provide information to representatives of their own government for different reasons. A report to the U.S. Congress in 2005 stated that Russia, China and India were at the top of the list of numerous countries targeting U.S. hightech companies.²⁵³

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²⁴⁸ Interfax (2010) 'Interior Troops Prevent Theft of Sensitive Info from Virology Laboratory', Interfax-AVN online, 11 March 2010.

²⁴⁹ Nasheri, Hedieh (2004) Economic Espionage and Industrial Spying, Cambridge Studies in Criminology (Cambridge, Cambridge University Press)

Mollman (2007) 'The Threat from Within', pp. 293-5.

²⁵¹ Nasheri (2004) Economic Espionage and Industrial Spying.

²⁵² Ibid.

Part 1010.
253 Rishikof, Harvey (2009) 'Economic and Industrial Espionage: A question of counterintelligence or law enforcement?', National Strategy Forum, summer, on the Internet: http://nationalstrategy.com/Programs/NationalStrategyForumReview/SpringSummer2009NSFRO http://nationalstrategy.com/Programs/NationalStrategyForumReview/SpringSummer2009NSFRO http://nationalstrategyForumReview/SpringSummer2009NSFRO <a href="nlineJournal/featureEssayEconomicandIndustrialEspionage/tabid/189/De

Russia makes no secret of its ambitions to gather S&T intelligence for its own interests. The Russian intelligence services are obliged by federal law 'to assist the country's economic development, scientific and technical progress and to ensure the military-technical security of the Russian Federation'. 254 These words are echoed in the officially declared goals and tasks for the Foreign Intelligence Service (SVR).²⁵⁵ The 2010 annual threat assessment by Dennis C. Blair, Director of U.S. National Intelligence, singles out the Russian Federation as a significant intelligence threat. 'Russia continues to strengthen its intelligence capabilities and directs them against US interests worldwide. Moscow's intelligence effort includes espionage, technology acquisition and covert action efforts.'256 Together with China, Russia has been pointed out by other U.S. sources as carrying out this type of espionage. 257 According to the Russian defector Stanislav Levchenko's statement in 1992, high-tech industrial and economic intelligence became the main priority for the new Russian intelligence services. 258 The German national Security Service, the Bundesamt für Verfassungsschutz (BfV), in its 2008 annual report also acknowledged the Russian Federation as one of the main intelligence actors in Germany, in particular in the areas of science and technology.²⁵⁹ According to Jonathan Evans, the head of MI5, in 2007, the scope of the Russian intelligence gathering was equal to the Soviet effort during the Cold War. He also stated that Russian intelligence services were in particular interested in British science and technology.260

Historically, Russia and China have been mentioned as examples of intelligence services specifically targeting high-tech civilian R&D. There have been numerous reports that industrial espionage activities have not declined since the end of the Cold War, but have only been retargeted to focus even more on high-

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²⁵⁴ Russian Federation (1995) [Federal Law 'On Foreign Intelligence'], No. 5-Φ3, Article 5.

²⁵⁵ See for instance the Foreign Intelligence Service, Sluzhba Vneshnei Razvedki SVR website, on the Internet: http://www.svr.gov.ru/svr_today/celi.htm.

²⁵⁶ U.S. Director of National Intelligence (2010) Annual Threat Assessment of the US Intelligence Community for the Senate Select Committee on Intelligence, Office of the Director of National Intelligence, 2 February 2010, p. 43.

²⁵⁷ Ackerman, R. (2009) 'Threaths Imperil the Entire U.S. Infrastructure. From the military to the economy, the country is open to vast damage', SIGNAL, *AFCEA International Journal*, July 2009.

²⁵⁸ Sibley, Katherine A. S. (2004) Red Spies in America: Stolen secrets and the dawn of the Cold War (Lawrence, Kansas, University Press of Kansas), p. 233.

²⁵⁹ Bundesamt für Verfassungsschutz (2009) Verfassungsschutzbericht 2008, Bundesministerium des Innern, Berlin, 2009, p. 308 and 335.

Brogan, Benedict (2007) 'Soaring Number of Russian and Chinese Spies Diverting MI5 Attention from Terror Fight', *Daily Mail*, 7 November 2007, on the Internet: http://www.dailymail.co.uk/news/article-491830/Soaring-number-Russian-Chinese-spies-diverting-MI5-attention-terror-fight.html# (retrieved 27 January 2007); and Westerlund, Fredrik (2010) *Russian Intelligence Gathering for Domestic R&D – Short-cut or dead-end for modernisation*?, FOI MEMO 3126 (Stockholm, FOI).

tech (and not just defence-related) R&D. U.S. government agencies have warned that the security challenges for the biotechnology and pharmaceuticals industries will increase exponentially in the foreseeable future. 261 According to Kevin Coleman in a report, 'International espionage activities have targeted the biotech industry with their eyes on data from later stages of research'. ²⁶² The U.S. House of Representatives Permanent Select Committee on Intelligence has stated that foreign competitors are stealing trade secrets from American pharmaceuticals and biotech companies. ²⁶³ It is difficult to say how widespread the industrial espionage activity is that targets biotechnology activities, but it can be assumed that both companies and states are involved.

²⁶¹ HSNW (2009) 'Bioespionage New Threat to U.S. Economy', Homeland Security Newswire, 9 December, on the Internet: http://homelandsecuritynewswire.com/bio-espionage-new-threat-us- economy (retrieved 20 January 2010); and Rishikof (2009) 'Economic and Industrial Espionage'. Goleman, Kevin G. (2009) Bio Espionage: They're after the data, *Data Voice Solutions*, on the

internet: http://data-voice-solutions.tmcnet.com/topics/security/articles/70394-bio-espionagetheyre-after-data.htm (retrieved 10 February 2010).

HSNW (2009) 'Bioespionage New Threat to U.S Economy'.

9 Government Programmes, Economic Zones and Techno-parks for the Development of Russian Biotechnology

There have been a large number of initiatives over the years to promote biotechnology, including the programme for Development of Biotechnology 1994–2000²⁶⁴ and the Russian Federation's policy for developing science and technology in the period from 2002 to 2010. 265

Other programmes included The National Technological Base 2002–2006, The Life Sciences, Nanotechnology Development (including nano-biotechnology), The Human Genome, Biodiversity, Gene Diagnostics and Gene Therapy, Vaccine, New Generation of Vaccines and Medical Diagnostic Systems of the Future, New Drugs and Protection against Pathogens, Prevention and Control of Socially Significant Diseases, Virus Infection, Diabetes, TB, HIV Infection, Sexually Transmitted Infections, Viral Hepatitis and Health. The impact of these programmes, in those cases where they have been funded at all, is difficult to assess and whether they have been monitored with regard to their results or efficiency is an open question.

Russia had also established around 20 special economic zones (duty-free zones, or high technology zones). Four are aimed at innovative production and there is at least one in Tomsk focusing on biotechnology, opened in 2008, which has close cooperation with the Novosibirsk technology park. These zones were developed very slowly, and were in many cases given unrealistic plans. They were criticized for being used for tax evasion by companies that exist only on paper and thus not bringing benefits to the regions. The special economic zones also offered few advantages for foreign firms. The problems were well known: examples were Russia's poor reputation on intellectual property rights, its weak innovation system, its low-tech image, and the lack of R&D-related finance as well as administrative inertia. In fact very few foreign firms

²⁶⁴ Rimmington (1995) 'On the Eastern Front'.

Lindblad, Anders et al. (2005) Russian Biological and Chemical Weapons Capabilities: Future scenarios and alternatives of actions, Report FOI-R--1561--SE, January (Stockholm, FOI) p. 42; and Security Council of the Russian Federation, Osnovy politiki Rossiiskoi Federatsii v oblasti razvitia nauki i tekhnologii na period do 2010 i dal'neishuiu perspektivu [Foundations for Russian Federation Policy for the Development of Science and Technology in the Period up till 2010 and Beyond], on the Internet: http://www.scrf.gov.ru/Documents/Decree/2002/30-03.html (retrieved 30 March 2002).

Tuominen, Karita and Eero Lamminen (2008) 'Russian Special Economic Zones', Turku School of Economics, Electronic Publications of Pan-European Institute, No. 18, on the Internet: http://www.tse.fi/FI/yksikot/erillislaitokset/pei/Documents/Julkaisut/Tuominen%20and%20Lamminen%201808%20web.pdf (retrieved 25 November 2009).

²⁶⁷ Ibid.

established themselves in the zones. These zones were given a limited time span and could be closed as early as in 2025. 268

Eight technology parks were planned in connection with large educational and research institutes to stimulate innovation in nanotechnology, biotechnology and IT.²⁶⁹ The state had allocated the equivalent of \$1.3 billion of the total cost of \$6 billion to build them.²⁷⁰ In 2006, the State Programme Building Techno-parks in the High Technology Sector of the Russian Federation was planned for 2006–2012; it was to establish techno-parks, in which biotechnology was included, in Moscow, Kaluga, Novosibirsk (biotechnology/bio-medicine), Nizhnii Novgorod (bio-medical technologies), St Petersburg, Tyumen, Tatarstan (biotechnology), Kemerovo and Obninsk (biotechnology/pharmacy). There were also so-called science cities, 65 in total, 29 of which were within the Moscow Region. Those with relevance for biotechnology are Pushchino, Koltsovo (Novosibirsk Region, biotechnology), Mikhurinsk (Tambov Region, plant cultivation), and Peter Dvorets (in St Petersburg, biology).

The development of biotechnology became a priority again for the government at the beginning of the 21st century. It has been so for the scientific community since the collapse of the Soviet Union. In 2004, Anatolii Vorobev, in his capacity as president of the Russian Society of Biotechnologists, called for the development of a new federal biotechnology programme. Reviving the domestic biotechnology industry was seen as a major challenge and as early as in 2002 the Interdepartmental Committee on Biotechnology decided to initiate a Strategy for the Development of Biotechnology in Russia. During the process of developing the strategy, it was concluded that many facilities needed reconstruction, which would only be possible if major investments were made. There was a need for state and private partnerships and for improvements of the innovation system. The required infrastructure for commercialization of biotechnology had to be established as well as a transparent and clear regulatory framework. Significant foreign investments in the biotechnology area had to be attracted. In addition, public awareness had to be raised on the potential benefits

²⁶⁸ Liuhto, Kari (2009) 'Russia's Innovation Reform – The current state of special economic zones', Review of International Comparative Management, vol. 10, Issue 1.

Review of International Comparative Management, vol. 10, Issue 1.

269 Techno-parks information, on the Internet: http://technopark.al.ru/ (retrieved 25 November 2009).

²⁷⁰ RIA Novosti (2008) 'Russia to Build Eight Technoparks by 2012', RIA Novosti, 6 February 2008.

²⁷¹ Russian BW Monitor (2004) 'Vorobev Calls for Russia to Launch Federal Biotechnology Programme', *Russian BW Monitor*, 13 October, on the Internet: http://www.russianbwmonitor.com (retrieved 14 October 2004).

This work has progressed very slowly and it might be adopted by the government <u>during 2010</u>.

of biotechnology and ethical issues had to be discussed.²⁷³ The Duma in 2005 formulated the most urgent priorities for biotechnology as well as practical recommendations to address them. In particular, the Duma focused on the creation of a more favourable investment climate, development of innovation infrastructure (including venture financing), renovation and creation of new plants, and harmonization with international standards.²⁷⁴

9.1 The National Programme for the Development of Biotechnology in Russia, 2006–2015

An initiative by the Russian Society of Biotechnologists, entitled the National Programme for the Development of Biotechnology in Russia, 2006-2015, was established in February 2005. 275 The programme was a public-private partnership involving many organizations and aimed to develop both governmental and non-governmental measures to create the environment necessary for the further development of fundamental and applied biotechnology. The programme consisted of eleven sub-programmes, including regional programmes and special priority projects. It was to support science centres, as well as regions focused on biotechnology and biology. The programme was planned to be implemented in three stages – I for 2006–2008, II for 2009–2011 and III for 2012-2015. It was structured into four sections - priority national projects, federal projects, regional projects and targeted projects. The Third All-Russian Congress of Biotechnology in 2005 agreed to present the programme for the Duma Expert Council on Biotechnology of the Committee for Industry, Construction and Science and Technology and the Russian Government. The aim was to revive the biotechnology industry in Russia. The national priority projects were the ones which would be crucial to national security.

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²⁷³ Biomac (2007) 'Problems of Strategic Planning of Development of Biotechnology in Russia', non-commercial partnership Biotechnology Consortium for Medicine and Agroindustrial Complex, 23 May 2005, on the Internet: http://www.Biomac (retrieved 20 March 2007).

Mezenova (2008) 'Biotechnology in Russia: Innovation sectors in research and industry', Russian Society of Biotechnologists, Presentation at German Russian Workshop in Biotechnology, Hanover, on the Internet:

http://www.owwz.de/fileadmin/Biotechnologie/BioVeranst/Biotechnica_2008/Mezenova.pdf (retrieved 10 March 2009).

Russian Society of Biotechnologists (2005) National Program, Biotechnology in the Russian Federation, 2006–2015, Based on Public-Private Partnership, Russian Society of Biotechnologists, on the Internet: http://bioros.tmweb.ru/papers-society/programma_razvitia.doc (retrieved 24 February 2009).

In order of importance they were:

- the protection of industries and the environment;
- the protection of collections of microorganisms and genetic resources;
- the production of bio-fuels (based on ethanol);
- the production of starter materials for the biological and chemical industry (biodegradable polymers, biocatalysts etc.); and
- large-scale production of protein feed for livestock and poultry.

The national priority projects should not be more than five to seven in number, and should be based on being interdisciplinary and interdepartmental in nature. The results of these projects, the programme states, would have a major economic impact.

Federal projects would focus on medical biotechnology (essential drugs, hormones, cytokines, therapeutic monoclonal antibodies, vaccines and stem cell technology), food and agricultural applications of biotechnology, post-genomic technology, bioinformatics, biochips and nano-biotechnology. The programme would also provide new methods for protection against bioterrorism. It would further improve the agricultural sector and promote developing transgenic plants and animals. In the area of food biotechnology the programme was to develop functional foods²⁷⁶ and carry out a project on biotechnology seafoods. In the field of environmental biotechnology, remediation measures were a priority.

The main goal of the programme was to integrate the efforts of the state, business and the scientific community to develop a modern biotechnology industry and a knowledge-based bio-economy. Implementation would focus on national and regional priority biotech projects dedicated to the solution of economic and social problems. The programme involved a public–private partnership with funding estimated at around 150 billion roubles. The results if the programme was successfully implemented would be to replace most imports of essential medical supplies.

The first step - 2006-2008 - involved the evaluation of the Russian biotechnology industry, establishing databases and setting priorities in order to create legal and economic conditions for the biotech industry, encouraging innovations and strengthening protection of intellectual property rights. Regional

²⁷⁷ Saltykov, B. G. (2007) 'Breaking Up Is Hard To Do', *Nature*, Vol. 449, 4 October 2007, pp. 536-7.

²⁷⁶ Functional food contains substances affecting one or several body functions in positive way. Certain nutrition-related illnesses such as cardiovascular diseases or some cancers, diabetes or osteoporosis can be prevented or positively affected by functional food.

pilot projects would be initiated in the first step in five to seven regions out of a total of 30 regions. ²⁷⁸ Some examples of regional projects (2008) were:

- Chuvash Republic (Lysine, citric and lactic acid production plants)
- · Kaliningrad Oblast'
- Kirov Oblast'
- · Saratov Oblast'
- Tomsk Oblast'
- Novosibirsk Oblast'
- · Belgorod Oblast'
- · Kaluga Oblast'
- Republic of Tatarstan (bioplastics and biopolymers)
- Tyumen Oblast'
- Nizhnii Novgorod
- St Petersburg
- Moscow, Moscow Oblast' (RecInsulin and biopharma generics)
- Krasnodar Krai
- Krasnoyarsk Krai
- Primorskii Krai

The second step – 2009–2011 – was to implement priority projects with a focus on food additives and security, clean energy production, and improving the quality of life using biotechnology. Large-scale regional programmes were to be implemented in 30 regions. Domestic production of biological diagnostics, vaccines, treatment and prevention methods for socially significant diseases were to be initiated. Another goal was to further improve the innovation system for biotechnology and to create a modern system for training in biotechnology.

During the third step – **2012–2015** – there was to be widespread implementation of the national priority projects. This would include targets such as large-scale production of biofuels; use of ethanol in fuel mixes like biodiesel should account for 5 per cent of the country's energy needs. Thirty per cent of imported goods were to be replaced by domestic production of enzymes, polysaccharides and biological pesticides. It would also involve implementation

²⁷⁸ Rabinovich (2007b) 'Biotech in Russia', pp. 778-84.

of the Priority Directions of Scientific and Practical Biotechnology (2009–2015) federal targeted programme, focusing on environmental biotechnology and improving biosafety. The introduction of the latest advances in genomics, nanotechnology, bioinformatics and the establishment of a system of biological resource centres were also envisaged in the programme. ²⁷⁹ To implement the programme the leading research institutes, ²⁸⁰ academic bodies and companies (JSC Biopreparat, OJSC Vostok, LLC Bioprocess, JSC East, OOO HimRar etc.) as well as the Ministry of Defence Institute of Microbiology in Kirov were to be engaged. The programme would also provide for extensive international cooperation (with the CIS countries, the EU, China, India, U.S. and Latin America). To implement the national priority projects would require 1 billion roubles and thus a special government resolution would be required. It was estimated that the total funding needed would amount to 150 000 million roubles. of which 15 000 million roubles would come from the federal budget (10 per cent), 45 000 million roubles would come from the budgets of the subjects (constituent parts) of the Russian Federation (30 per cent) and 90 000 million roubles would come from extra-budgetary sources (60 per cent). 281 The national programme for the development of biotechnology in 2006-2015 would receive 60 per cent of its funds from extra-budgetary funds.

9.2 The Development Strategy for the Biotechnology Industry in Russia 2010–2020

In 2002 the government regarded the development of the biotech industry as a priority for strengthening the Russian economy. Biotechnology was also included in the Strategy for the Socio-Economic Development of the Russian Federation until 2020. A document entitled *The Development Strategy for the Biotechnology Industry in Russia 2010–2020* was prepared based on previous work for the National Programme for the Development of Biotechnology in Russia 2006–2015. The Strategy was to be coordinated by the Ministry of Industry and Trade with an expected budget of €30 billion. The ruling party, United Russia, had adopted a special project – Biotechnology – to support this initiative. At the Meeting of the Russian Society of Biotechnologists in December 2008, it was

²⁷⁹ Ibid., pp. 778-84.

²⁸⁰ M. M. Shemyakin and Y. A. Ovchinnikova Institute of Bioorganic Chemistry RAS, Pushchino Research Centre RAS, N.I. Vavilova Institute of General Genetics RAS, GosNIIgenetika and Ministry of Defence Institute of Microbiology.

Russian Society of Biotechnologists (2005) National Program, Biotechnology.

²⁸² Mezenova (2008) 'Biotechnology in Russia'.

²⁸³ Ibid

noted that biotechnology was seen as a strategic area and one of national security importance for scientific and technological progress in Russia.²⁸⁴

The Russian Government was to decide in early 2010 on the Development Strategy for the Biotechnology Industry in Russia 2010–2020. 285 At a meeting in December 2009, the Union of Enterprises of the Biotechnology Industry discussed a final draft of the Strategy and it was agreed to present this to the government.²⁸⁶ Earlier, in October 2009, a parliamentary hearing in the Duma was devoted to discussing the improvement of legislative support of the biotechnology industry and the development strategy for the biotechnology industry. The hearing was held with the participation of government and public figures, leading experts, Duma deputies, representatives of ministries and departments, industrial managers, the Academy of Sciences, the Academy of Medical Sciences and the Academy of Agricultural Sciences, as well as other scientific organizations and the media. This was the first parliamentary hearing on biotechnology in the Duma for ten years. During the hearing, an assessment, included as part of the Strategy, was presented of the significance and status of the biotechnology industry, and of the concrete recommendations proposed for its development, including legislative support needed. In the recommendations adopted from the hearing, the main results of the Development Strategy for the Biotechnology Industry were:

- 1. Improvement of the competitiveness of oil, fuel, chemical, forestry/wood, food and medical industries through innovations.
- 2. Import substitution of vital and essential medicines, food and feed products, the key for drug and food safety.
- 3. Improvement of health care through the introduction of new methods for the diagnosis, prevention and treatment of diseases.
- 4. Increasing the share of renewables in the energy mix.
- 5. Improving the environmental situation in Russia by reducing emissions (discharges) of pollutants in the environment and improving conservation of biodiversity.

²⁸⁴ Parliamentary hearings (2009) Working Papers for Development of the Strategy for the Biotechnology Industry; and Moscow Newspaper Industry (2008) 'Perspectives for Biotechnology', *Moscow Newspaper Industry*, No. 40, Issue 463 (December).

Russian Society of Biotechnologists (2009) [Draft for Strategy for the Development of the Biotechnology Industry in Russia 2010–2020] (in Russian), on the Internet:

http://www.biorosinfo.ru/papers-society/Strategy_Bioindustry.pdf (retrieved 16 December 2009).

286 Union of Enterprises of the Biotechnology (2009) [Minutes from the Meeting of the Union of Enterprises of the Biotechnology] (in Russian), 4 December 2009, on the Internet:

http://www.biorosinfo.ru/kalendar%20meropriyatiy/Soveschanie_Sojuz_Biotech/Protokol_sobranija.pdf (retrieved 17 December 2009).

- 6. More efficient use of bioresources in Russia.
- 7. Creation of new jobs for urban and rural populations.
- 8. Support for an innovation-driven economy both through the introduction of the technologies from domestic research and through technology transfer from abroad.
- 9. Development of related industries, especially agriculture, by creating additional demand for their products from the biotech industries.
- 10. Alignment of the regions through involvement in the implementation of a strategy for economically depressed regions, including establishing biotech clusters.
- 11. Building a foundation for long-term sustainable economic growth in Russia. ²⁸⁷

The main developers of the Strategy, which was the result of work done since 2004, were the Russian Society of Biotechnologists with more than 3000 scientists and experts in 57 regions of the country, with support from the Union of Enterprises of the Biotechnology Industry, as well as the Council of Experts on the Biotechnology and Pharmaceutical Industries in the Duma's Committee on Industry.

In the background papers for the Strategy, the current situation of Russian biotechnology was assessed and future targets proposed. The Russian market for products in the red (biopharmaceuticals and biomedicine) biotechnology area was estimated to amount to between 60 and 90 billion roubles per year, but this demand was being met mainly through imports in 2009. According to the Ministry of Industry and Trade of Russia, only 5 per cent of biotech substances used in the production of final formulations was produced in Russia. Although the trend was weak in this area there might be some positive signs.

In the area of white biotechnology (biomaterials),²⁹⁰ in 2008 there were few examples of such R&D in Russia. However, one area – the hydrolysis industry for production of some chemical compounds, such as furfural – could be one

²⁸⁷ Parliamentary hearings (2009) Working Papers for Development of the Strategy for the Biotechnology Industry.

²⁸⁸ Ibid.

²⁸⁹ Ibid.

Red biotechnology is related to ensuring human health and the potential correction of its genome, as well as the production of biopharmaceuticals (proteins, enzymes, antibodies); green biotechnology aims to create and production of genetically modified (GM) plants resistant to biotic and abiotic stress; white biotechnology covers methods of agriculture and forestry; industrial production of biofuels, food processing, and applications for chemical and petroleum industry; grey biotechnology is linked to environmental management, bioremediation; and blue biotechnology is related to the use of marine resources and raw materials.

such example. Promising areas were the production of biofuels and food biotechnology. One of these research areas was the development of 'secondgeneration' biofuels based on non-food biomass, such as sawdust, straw or biowaste for energy plants. One of the main emphases for food biotechnology was the production of enzymes for use in almost all subsectors of the food industry, such as meat, confectionery, bakery, dairy, brewing, alcohol and starch. In 2008 the volume of enzymes produced in Russia was about 15 per cent of the 1990 level, and the share of Russian producers on the market for enzymes did not exceed 20 per cent. Domestically-produced enzymes were mainly used in feed production as manufacturers of food for human consumption preferred imported ingredients. Examples of leading enterprises for enzyme production were JSC Vostok (Kirov Region), LLC PO Sibbiofarm (Novosibirsk Region) and OJSC Moscow Plant Rennet (Moscow). However, many of the industries in this area were using outdated technologies and were not competitive. Russia was stronger on production of dietary supplements and there were nearly 8000 names of dietary supplements, of which no less than 60 per cent were produced in Russia. Around 900 companies were engaged in manufacturing dietary supplements, such as JSC Evalar (Altai Region), OJSC Diode (Moscow), OOO Fora-Farm (Moscow). However, domestic production accounted for no more than 30 per cent of the market in value terms.

Concerning green biotechnology (agro-food products), growing genetically modified crops in Russia is not prohibited by law. However, GM crops have not been grown on an industrial scale in Russia due to tensions over the question of GMOs and other obstacles. Russia permits the use in food of 15 lines of genetically modified crops (eight lines of maize, three lines of soybean two varieties, one line of sugar beet and one line of rice). The practice of regulation of the cultivation and processing of GM crops in 2009 created non-competitive advantages for imports and hampered the development of Russian green biotechnology. Using biotechnology methods, it would be possible to achieve faster growth of trees which would be less prone to viral and bacterial diseases. One example is the development of transgenic trees. The Russo-Swedish company OOO Baikal Nordic (Republic of Buriatia) in 2009 planned to implement a project worth 1.5 billion roubles. The project included the establishment of a nursery with genetically modified species.

The area of grey biotechnology includes bioremediation for cleaning soil and water from contamination such as oil spills and oil products. Examples of Russian products are Putidoyl, Oleovorin, Naftoks, Uni-rem, Roder, CentrIN, Psevdomin, Destroyl, Micromycetes, Leader, Valentis, Devoroyl, Rodobel, Rodobel-T, Ekonadin, Desna, and Simbinal, but the area has not been strongly developed, at least not on an industrial scale. Promising areas for Russia in 2009 were mineral leaching and methods for improving oil recovery using microbial processes. There were several products that had been said to be superior to

foreign counterparts in tests, but they were not brought forward for industrial production.

One important aspect in the Strategy was that it proposed to establish a Council for Biotechnology to monitor the implementation of the Strategy. This was to include representatives from the Ministry of Industry, the Ministry of Education and Science and other federal agencies. In a similar manner, regional coordination bodies were to be created. According to the Strategy, Russia still needed a series of changes in the legislation to promote activities in the biotechnology area. In addition, there was a need to reform the education system and to encourage the recruitment of young scientists to biotechnology. The Strategy furthermore pointed out that biotechnology industries were 'often objects of special danger', and chemical, biological and other safety must be ensured.²⁹¹ The new Strategy will be focused on setting targets and then stakeholders will develop the content, in contrast to earlier practice when a top-down approach was used that appeared not to be successful.²⁹² The Strategy was to be adopted during 2010 and its success would depend on the financial resources allocated and effective monitoring of the implementation process. Experiences from earlier programmes were not very positive and the global financial crisis threatened to prevent the government from providing enough resources at this time.

Table 7 lists the targets set up in the Strategy for the different areas of biotechnology. From this it is clear how ambitious the Strategy was. For example, the number of companies that complied with the international GMP standards was to increase from 2 per cent in 2010 to 80 per cent in 2015 – that is, within five years, which is hardly realistic. Russian companies have been slow to adopt these standards, in spite of regulations stating that they are obliged to comply if they want to sell pharmaceuticals in Russia. The number of research groups working in biotechnology is to increase five-fold between 2010 and 2020, which would mean very large investments in biotechnology R&D. The number of domestic drugs for clinical trials is to increase from five in 2010 to 30 in 2020, which is probably not realistic. The target of a reduction in the share of imports of biopharmaceuticals in consumption – from 90 per cent in 2010 to 70 per cent in 2020 – is also very ambitious and will be difficult to achieve. How realistic these targets are is therefore open to debate, but they give a clear indication of what the aims are.

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²⁹¹ Society of Biotechnologists (2009) [Draft for Strategy for the Development of the Biotechnology Industry in Russia 2010–2020] (in Russian), on the Internet: http://www.biorosinfo.ru/papers-society/Strategy_Bioindustry.pdf (retrieved 16 December 2009).
²⁹² PIA November (2007) (Press) of Business (2007)

¹⁹² RIA Novosti (2007) 'Russia to Produce Biotech Drugs in 1.5 yrs – Health Minister Zurabov', *RIA Novosti*, 7 May, on the Internet: http://en.rian.ru/russia/20070323/62518822.html (retrieved 13 May 2007).

Area	2010	2015	2017	2020
Science & education				
Increase in biotech				
Research groups	-	4 x	4.5 x	5x
Inventive activity	-	2.5 x	3.5x	4x
Share of scientists under				
the age of 39	35%	37%	38%	38%
Red biotechnology				
No. of biomedical service,				
Equipment companies	5	10	15	20
No. of biopharmaceuticals				
Companies	2-3	6-8	10-15	15-20
Biopharmaceuticals				
share of imports	90%	85%	80%	70%
Plants achieving GMP				
GLP standards	2%	80%	100%	100%
Number of drugs for				
clinical trials	5	15	20	30
Studies in diagnosis				
& treat. Active phase	10	20	30	40
White biotechnology				
Replacement % biofuel				
in diesel/petrol	-	2.5	3.5	5.0
Share of renewable				
energy in electricity				
Production	1.5%	2.5%	-	4,5%

²⁹³ Russian Society of Biotechnologists (2009) [Draft for Strategy for the Development of the Biotechnology Industry in Russia 2010–2020].

Table 7. Continued, Performance Targets for the Development Strategy for the Biotechnology Industry in Russia, 2010-20202015 2017 Area 2010 *2020* Food protein products tonnes 500 *750* >1000 Glucose, fructose tonnes 200-300 *500 750* >1000 Lysine tonnes 15 25 *30* Share of market for Russian-produced 26% 50% 60% 65% amino-acids Share of market for Russian-produced food enzymes *30% 50%* 60% 70% Biomass feedstock for Chem. Petroleum ind. 0% 5% *10%* Part biodegradable packaging in food ind. 5% *15%* 30% Green biotechnology Increase in yields 0 20% 40% Agriculture Grain harvest in million tonnes 85 102 120 Blue biotechnology Plants producing 3 biofuel from algae 0 1 3% 10% Fish farm increase 0,2% 1%

10 Biofuel Developments

Gas and oil are very important for Russia today, but the world was going to switch over to biofuels. This was recognized by President Medvedev in his annual address to Parliament in 2009:

Instead of a primitive raw materials economy we will create a smart economy producing unique knowledge, new goods and technology of use to people... One of the most promising areas is to make use of the widespread bio-resources we have, above all timber, peat, and industrial waste, as energy sources. ²⁹⁴

Vladimir Putin agreed with this and had already in 2008 stated that an increase in the proportion of energy derived from alternative sources, from 1 per cent to 4.5 per cent of all energy produced in the country, was desirable by 2020. It can be added that according to a representative of Lukoil oil production had peaked in Russia in 2008.²⁹⁵ In 2008 the Duma proposed a state programme for the production of 1.8 million tonnes of bioethanol per year. Several bioethanol plants were to be built.²⁹⁶ There is a historical background as about 30 Russian plants that produced ethanol from non-crop raw materials went bankrupt with the collapse of the Soviet Union due to inefficient technology.

Demand for Russian raw materials for biofuel production in Europe grew in 2008. Russia had an advantage when it came to producing biofuel in sufficient amounts, in contrast to the European countries which would have to use approximately one-third of their farmland to grow biomass for biofuel production. Biofuel plants were planned on a large scale in Russia and their products would be aimed primarily at the European market.²⁹⁷ The hope was to make European countries dependent on Russian biofuels as an alternative to

²⁹⁴ Russian President (2009) 'Presidential Address to the Federal Assembly of the Russian Federation', The Kremlin, Moscow, 12 November 2009, on the Internet: http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009)

²⁹⁵ Financial Times (2008) 'Oil Production in Russia Has Peaked, Warns Lukoil Executive', Financial Times, 15 April 2008; and ITAR-TASS (2007) 'Major Education and Training Centres Should Be Established – Putin', ITAR-TASS World Service, 28 November 2007, on the Internet: http://www.biofuels.ru/bioethanol/news/major_education_and_training_centres_should_be_established_-_putin/ (retrieved 10 March 2009).

Russian Biofuels Association (2009) 'Duma Calls for State Program on Bioethanol Production', Russian Biofuels Association, on the Internet:

http://www.biofuels.ru/bioethanol/news/duma_calls_for_state_program_on_bioethanol_productio_n/ (retrieved 14 October 2009).

²⁹⁷ ITAR-TASS (2007) 'Putin Calls for Stimulating Biofuel Production', *ITAR-TASS*, 28 November 2007, on the Internet:

http://www.biofuels.ru/bioethanol/news/putin_calls_for_stimulating_biofuel_production/(retrieved 10 March 2009).

fossil fuels. Few countries had as large a biofuel potential as Russia, Putin said, given its gigantic territory. With the advent of next-generation bioconversion technologies, which can turn lignocelluloses biomass such as wood and grass into liquid and gaseous biofuels, Russia, with its vast taiga and tundra, indeed emerged as one of the largest potential producers. If grain prices were to reach \$200 per metric tonne and oil prices \$100 per barrel, biofuel production in Russia would become profitable. Putin proposed in 2008 that Russia should be among the world's top producers of biofuels. Researchers in Russia were close to developing a technology to make fuel out of timber waste that would be as efficient as conversion of food crops into fuel. Plans to redirect some of the country's crop harvests to make fuel should not increase bread prices because there was room to grow larger harvests. Russia had about 40 million hectares of unused arable land.

The biofuel sector in Russia has only made slow progress although the prospects were good. The main reasons for this appear to be the lack of government policy and financial support rather than lack of technical capabilities. Other reasons are the relatively low cost of traditional energy sources, lack of coordination among government agencies and lack of support for R&D initiatives in this area. There was, however, one initiative, Bioenergy Development in Russia, which the ministries of Energy and Agriculture started, to prepare a draft for legislation in 2008 to stimulate production of bioenergy from plant materials. The Minister for Agriculture in 2007 strongly advocated developing Russian biofuels, linking it to the growth in rapeseed production, and listed twelve cities as sites for future biofuel production.

There were plans in 2008 to develop biofuel production, which included the construction of 30 new plants to make ethanol, as well as upgrading existing

²⁹⁸ Russian Biofuels Association (2007) 'Putin Encourages Farmers to Produce Biofuels: Russia as green energy giant', Russian Biofuels Association, 5 November 2007, on the Internet: http://www.biofuels.ru/bioethanol/news/putin encourages farmers to produce biofuels russia as a green energy giant/ (retrieved 10 March 2009).

²⁹⁹ Ethanol & Biodical Nature (2000) (P. 1997) (1998) (1998)

²⁹⁹ Ethanol & Biodiesel News (2008) 'Russian Government to Back 30 New Biofuel Plants', Ethanol & Biodiesel News, Vol. XX, No. 17 (24 April 2008), on the Internet: http://www.biofuels.ru/bioethanol/news/russian_government_to_back_30_new_biofuel_plants/ (retrieved 10 March 2009).

Pristupa, Alexey O., Arthur P. J. Mol and Peter Oosterveer (2010) 'Stagnation Liquid Biofuel Developments in Russia: Present status and future', *Energy Policy*, online (in Press) on the Internet: http://www.enp.wur.nl/NR/rdonlyres/E783B567-4ED0-48B5-9DD4-0C50F2568790/102486/AlexeyOosterveerMol.pdf (retrieved 10 March 2010).

Smith, Mary E. and Marina Muran, Russian Federation Bio-Fuels Current Update 2008, GAIN Report No. RS8092. USDA Foreign Agriculture Service. 1 December 2008.

President of the Russian Federation (2007) [Beginning of Working Meeting with Minister of Agriculture Alexei Gordeev] (in Russian), The Kremlin, Moscow, 27 November 2007, on the Internet: http://archive.kremlin.ru/text/appears/2007/11/152241.shtml (retrieved 26 November 2009).

facilities. The aim was to produce 2 million tonnes per year (production was 0.6 million tonnes per year in the beginning of 2009).³⁰³ The Russian president has indicated that good business conditions should be created for biofuel production and the goal for the domestic production of biofuels to replace fossil fuels was for³⁰⁴

- 2012, 5 per cent of fossil fuel;
- 2015, 10 per cent of fossil fuel; and
- 2020, 20 per cent of fossil fuel.

A special company, Biotechnology Corporation, JSC, was established for the production of bioethanol and biobutanol based on cellulose. About twelve plants would be built with a total capacity of 2 million tonnes per year of biofuels by 2012. Around 10–20 biorefineries for processing of grain in Tartarstan, Omsk, Tomsk, Krasnovarsk, Volgograd, Krasnodar, Kirov and Chuvash, and elsewhere, would be built with a capacity of 500 000 to 1 million tonnes of processed feedstock. Every cluster would include between three and five different plants for bioethanol, starch, glucose-fructose syrups, gluten and so on. 305 Biofuel production in Russia would be possible for diesel biofuel based on sunflower and oilseed rape oil, bioethanol, sugar beet, corn, wood and biogas, waste materials from animal production, and food and wood processing. The Russian Federation already produces approximately 1–2 per cent of the world's biofuel.³⁰⁶

Russian Government officials have in many cases voiced their support for largescale production of biofuels in Russia as an alternative to fossil fuels. This has, however, not been followed by the new legislation needed to promote this, according to analysts. It can be questioned whether Russia really can compete with foreign producers of biofuels such as Brazil. The emerging Russian biofuel industry's export orientation is driven by the growing demand for biofuel in Europe and other nations. Production volumes of biofuel sources were still small in 2007, and had not yet affected Russia's domestic grain and oilseed prices. However, given the relatively high cost of production and transportation, unstable weather conditions, and limited land resources for grain and oilseed

³⁰³ ClimateIntel (2009) 'Biofuel Developments in Russia: Part 2 Political Responses', ClimateIntel, 23 June 2009, on the Internet: http://climateintel.com/2009/06/23/biofuel-developments-in-russiapart-2-political-responses/ (retrieved 10 October 2009).

³⁰⁴ President of the Russian Federation (2007) [Beginning of Working Meeting with Minister of Agriculture1.

Mezenova (2008) 'Biotechnology in Russia'.

³⁰⁶ Kolchinskij, J. L. (2008) 'Problems of Development of Bio-energetics in the Russian Federation', Agronomy Research, Vol. 6 (Special issue), pp. 221-7, on the Internet: http://www.eau.ee/~agronomy/vol06Spec/p6S06.pdf (retrieved 10 December 2009)

production in Russia, substantial increases in biofuel production would affect domestic grain markets in the long run. ³⁰⁷

Examples of projects initiated 2008:

- The Titan group (20 companies specializing in timber processing) invested \$273 million in 2008 in a bioethanol plant in Priirtyshe, Republic of Adygea, southern Russia.
- The Metasintez company was to invest € 220 million in a biofuel plant in Dmitrovska, Tambov Region, to be ready in 2011 with a capacity of 250 000 metric tonnes per year for export to Europe.
- In Altai, southern Siberia, Rebrikhinskii District, a bioethanol plant costing \$220–290 million was built by Pava in 2008 with a capacity of 100 000 tonnes per year.
- In Tartarstan, at Omsk, a bioethanol plant was constructed in 2009 for processing 1 million tonnes of crops per year.
- Ivanova-BioToplivo Ltd invested \$198 million in 2008 in a biofuel plant in Telkovo, Ivanovo Region, in central Russia.
- YugAgroInvest planned to invest \$32 million in a biofuel plant in 2008 with a capacity of 220 000 tonnes per year in Nevinomyssk, Stavropol Region.
- Biotechnology Corporation was to invest \$307 million in 2008 in three biofuel plants in the Krasnoyansk area.
- In Irkutsk the first biobutanol plant was opened in 2008, supported by the United Industrial Corporation Oberonprom.

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³⁰⁷ Vassilieva, Y., K. Svec and C. Brown (2007) Russian Federation Bio-Fuels Annual 2007, GAIN Report No. R57044, USDA Foreign Agriculture Service, 6 April 2007, on the Internet: http://www.fas.usda.gov/gainfiles/200706/146291296.pdf (retrieved 10 March 2010).

11 The Fight against Infectious Diseases

Russia was facing a demographic crisis. Its population has decreased since 1992, when it was 148.7 million, by 0.7 to 1.0 million annually, and it will be around 122 million in 2030.³⁰⁸

The decline in population in Russia is serious and has important consequences for Russia's national security. The number of draft-age males, at its peak in 2003, will fall by half (from 6.5 million to 3.3 million 15- to 19-year-old males) by 2016, and poor child health is making the situation worse. Russia's Main Military Medical Directorate claimed in 2004 that physical or mental deficiencies rendered over a third of would-be conscripts ineligible for service. An estimate in 2005 indicated that by 2020, 15.2 per cent of the population would be over 65 years old and this would also put increasing pressure on health care and demand for medicines. The public health sector was declared a priority during Vladimir Putin's presidency and \$20 billion were spent on four national projects in 2006–2008. The difficulty was not the amount of money thrown at the problem but rather the fact that there was very little follow-up to see that it had been spent on the right things – a problem common in Russia.

There has been some debate about how infectious diseases might impact on the Russian health crisis. It has been estimated that the number of cases of infectious diseases each year in Russia is about 40 million, resulting in a socio-economic loss of 18 billion roubles. In 2002 there appeared clearly stated objectives for the fight against infectious diseases and in 2001 the Ministry for Health adopted a programme for protection against and control of socially significant diseases for 2007–2011. The goal of the programme was to reduce the incidence of

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Danishevski, Kirill and Martin McKee (2005) 'Reforming the Russian Health-care System', The Lancet, Vol. 365 (19–25 March), pp. 1012-14.

³¹⁰ RIA Novosti (2008) 'Russia Approves Chemical and Biological Security Programme Concept', RIA Novosti, 1 February (translated by NTIS, U.S. Deptartment of Commerce).

Ancher, S. (2008) 'Demographic Impact of HIV/AIDS in Russia: Projections, analysis and policy implications', *China and Eurasia Forum Quarterly*, Vol. 6, No. 4, pp. 49-79, on the Internet: http://www.isdp.eu/files/publications/cefq/08/sa08hivrussia.pdf (retrieved 9 October 2009).

Onishchenko, Gennady G. (2002) 'Main Goals and Objectives in Combating Infectious Diseases in the Russian Federation, Epidemiological Situation and Basic Detection of Activities for its Stabilization, All-Russian Congress of Epidemiologists, Microbiologists, and Parasitologists', Moscow, 26–8 March, Ministry of Health, 55-6, translated in Appendix D, pp. 93-5, in NAS (2006) Biological Science and Biotechnology in Russia, Controlling Diseases and Enhancing Security (Washington, DC, National Research Council of the National Academies, NAS Press); and Decision of the Board of the Ministry of Health of the Russian Federation, 20–21 March 2001, on 'Progress in Implementing the Concept for Development of the Healthcare System and Medical Science: Tasks for the periods 2001–2005 and 2006–2010', in Appendix C, pp. 89-92, in NAS (2006) Biological Science and Biotechnology in Russia.

diseases among the population, to improve and to introduce new methods to prevent disease, to develop better methods for early diagnosis and to increase the effectiveness of treatments of socially significant diseases and patients' rehabilitation afterwards. The programme was divided into nine sub-programmes including viral hepatitis, HIV/AIDS, tuberculosis, sexually transmitted diseases and diabetes. Some of these programmes are listed in table 8, indicating the part allocated to R&D.

Table 8. Targeted Subprogrammes 2007 ³¹² R&D Total				
(million roubles)		mRUB	mRUB	
Virus hepatitis	37.30	416.90		
Sexually transmitted infections	30.90	203.40		
HIV/AIDS	25.60	370.20		
Vaccine prevention	12.20	183.30		
Tuberculosis	26.80	1414.90		
Prevention and struggle against				
Socially significant diseases for 2007–2011	272.47	4229.47		

How important the HIV/AIDS epidemic is in this regard to the decreasing population is a subject for debate. The number of confirmed HIV/AIDS cases in Russia is a contentious issue. Since 2001, the prevalence of HIV in Russia, Eastern Europe and Central Asia has roughly doubled, making the region home to the world's most rapidly expanding epidemic. Russia has been internationally criticized for its handling of the HIV/AIDS epidemic and began to take serious measures to limit it in 2006. In recent years the situation has stabilized, with around 470 000 cases of HIV officially registered and probably 1 million actual infections. Other sources, including the United Nations Joint Programme on HIV/AIDS (UNAIDS), estimate the number at about 1–1.6 million. In Russia, over 10 per cent of all new HIV diagnoses during 2006–2007 were registered among prison inmates, with an overall prevalence in prisons at around 5 per

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³¹² For translated text, see on the Internet: http://fcp.vpk.ru/cgi-bin/cis/fcp.cgi/Fcp/ViewFcp/View/2007/214/ (retrieved 5 September 2009).

Twigg, Judyth (2009) 'U.S.–Russia Collaboration on Health, Moving toward Engagement', CSIS Global Health Policy Center, July 2009, on the Internet:

http://csis.org/files/publication/090730_Twigg_USRussiaCollaboration.pdf (retrieved 10 December 2009).

cent.³¹⁴ The official figures show an acceleration of growth in recent years and an increase in 2008 alone of more than 25 per cent. Ukraine and the Russian Federation were experiencing especially severe and growing epidemics, with an adult HIV prevalence that is higher than 1.6 per cent.³¹⁵ Some estimates indicate that AIDS mortality will grow from 72 000 to 250 000 people between 2010 and 2020.³¹⁶ Foreign donors, such as the World Bank and individual countries, including Sweden, have made substantial efforts to fight the disease from the year 2000. Russia also became a priority country in the U.S. anti-AIDS programme.

However, as late as in 2009 Russia still lacked a well thought-out strategy to meet its growing health problems, and in particular to halt the rapid increase of the HIV epidemic. In addition, according to official Russian statistics, around 123 000 persons are infected with tuberculosis; the WHO estimate is 182 000. Multidrug resistant tuberculosis (MDR-TB) is a major problem and cases of hepatitis C infection are also rapidly increasing. Russia ranks eleventh on the list of 22 high-burden tuberculosis countries in the world. After years of gradual decline, the incidence of TB (tuberculosis) doubled during the 1990s, although in 2000 the rate of growth in the number of new cases year on year decreased. Around 282 850 people died from TB between 1998 and 2007. Russia had the third largest number of multidrug-resistant MDR-TB cases in the world in 2007, with close to 43 000. 318

Influenza is a recurring problem in Russia, as in many other countries, and the country has become used to handling such outbreaks. In 2005 avian flu swept through Siberia, which caused concern for the poultry industry. There were incidences in 35 towns and villages. Around 11 000 birds died and the authorities

³¹⁴ 'HIV in Russia, Eastern Europe and Central Asia', Averting HIV and AIDS, on the Internet: http://www.avert.org/aids-russia.htm (retrieved 9 October 2009).

Vol. 361, p. 2132.

³¹⁵ UNAIDS and WHO (2009) AIDS Epidemic Update 2009, November, on the Internet: http://img.thebody.com/unaids/pdfs/2009 epidemic update en.pdf (retrieved 9 December 2009).
316 Webster, P. (2003) 'HIV/AIDS Explosion in Russia Triggers Research Boom', The Lancet,

³¹⁷ Leijonhielm, Jan et al. (2009) 'HIV/AIDS – ett underskattat problem' [HIV/AIDS: An underestimated problem], pp. 124-127, in Rysk militär förmåga i ett tioårsperspektiv: ambitioner och utmaningar 2008 [Russian Military Capacity in a Ten-year Perspective: Ambitions and challenges 2008], Report FOI-R--2707--SE (Stockholm, FOI); WHO (2007) Plan to Stop TB in 18 High-priority Countries in the WHO European Region, 2007-2015, WHO European Regional Office for Europe, Copenhagen; and WHO (2006) Update on HIV/AIDS in the European Region, Ensuring Universal Access to Prevention, Treatment, Care and Support Services, Technical briefing document 01A/06, WHO European Regional Office for Europe, Copenhagen, 12 September.

³¹⁸ USAID, 'Infectious Diseases, Russia', on the Internet:

http://www.usaid.gov/our_work/global_health/id/tuberculosis/countries/eande/russia_profile.html
(retrieved 9 December 2009).

had to kill 100 000 chickens to control the outbreak. ³¹⁹ The first case of 'swine flu' was reported in June 2009. ³²⁰ In November 2009, about 4563 cases of swine flu and 19 fatalities had been registered according to official statistics. Most of these deaths were due to pneumonia as a complication of the influenza. Mortality from influenza was high during 2008 as well, when 484 people died from pneumonia during the flu epidemic. The number of deaths from pneumonia in 2009 was 439 – not dramatically different compared to the previous year. One top Russian virologist suggested, however, that the health authorities drastically understated the number of cases of H1N1, or swine flu. This was fiercely rejected by senior health officials. This raised questions about Russia's claim that it was relatively unaffected by the recent pandemic. Public health chief Gennady Onishchenko accused the doctor who initiated the discussion (if Russian reports are accurate) of an 'informational terrorist act'. ³²¹ This discussion is by no means new in Russia and it can only be hoped that the authorities there will provide accurate information to the public health community in future.

In October 2009, Roszdravnadzor, Russia's federal service on surveillance in healthcare and social development approved two domestic H1N1 flu vaccines Influvir and Pandeflu under a fast-track procedure. The approval was solely based on the safety and tolerability of the vaccine with no major side-effects. Influvir is a live monovalent vaccine for intranasal administration, while Pandeflu is an inactivated adsorbed monovalent sub-unit vaccine for injection. Russia started to vaccinate the population against swine flu on 9 November 2009. It planned to produce 40 million doses of influenza vaccines against the new influenza A/H1N1 in 2009 in order to cover 30 per cent of the population in St Petersburg and at the production sites of Microgen in Irkutsk and Ufa. Russia also imposed a ban on imports of pork and beef from some areas due to the pandemic. In November 2009, a decrease in the number of flu cases was reported in sixteen Russian regions, including in Moscow. Gennady

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³¹⁹ Aris, B. (2005) 'Avian Influenza Remains a Cause of Concern', *The Lancet*, Vol. 366, p. 798, on the Internet: http://www.globalresearch.ca/index.php?context=va&aid=1050 (retrieved 9 December 2009).

³²⁰ Consular Affairs Bulletins (2009) 'Warden Message: Russia confirms first H1N1 influenza case', Consular Affairs Bulletins, Europe–Russia, 2 June 2009, on the Internet:

https://www.osac.gov/Reports/report.cfm?contentID=103021 (retrieved 8 December 2009).

Wall Street Journal (2009) 'Doctor Says Russia Understating Swine-flu Cases', Wall Street Journal, 23 September, on the Internet:

http://online.wsj.com/article/SB125366412674432421.html (retrieved 10 October 2009).

Influenza Pandemic (H1N1) (2009) (99), RUSSIA, A ProMED-mail post, 10 November, on the Internet:

http://apex.oracle.com/pls/otn/f?p=2400:1001:4655328219272162::::F2400_P1001_BACK_PAGE_F2400_P1001_ARCHIVE_NUMBER_F2400_P1001_USE_ARCHIVE:1001,20091114.3939,Y (retrieved 8 December 2009).

³²³ ITAR-TASS (2009) 'Onishchenko Press Conference', ITAR-TASS, 19 August 2009.

Onishchenko claimed that the situation in Russia concerning flu and acute respiratory diseases was under control despite alarming forecasts.³²⁴

The number of cases of Crimean Congo haemorrhagic fever (200 cases in 2006, 30 per cent more than in 2005)³²⁵ and West Nile fever had increased significantly in 2007³²⁶ as well as the number of cases of haemorrhagic fever with renal syndrome³²⁷ in areas previously affected. Each year there are around 500 cases of brucellosis, a number of cases of anthrax and plague in several areas.³²⁸ After almost two decades without domestic production of rubella vaccine for childhood immunization, licensed manufacture was announced at the beginning of 2006.³²⁹

The government also initiated a sub-programme – Vaccine prophylaxis (see Table 8) – with the aim of reducing the level of disease due to infections by means of specific prophylaxis. The programme aimed to improve the methods of prophylaxis, monitoring of implementation of preventive and anti-epidemic actions, and the transportation system for vaccines. It also involved further development and the introduction of pilot/experimental/trial forms of new vaccines. This included constructing and reconstructing specialized medical institutes and equipping them with modern medical and technical equipment.

Research and development activities related to biotechnology were included in the sub-programmes (Table 8), for example, in the task of developing and introducing modern methods of prophylaxis, vaccines, diagnostics, treatment and rehabilitation based on high-technology solutions. In the programme, Rospotrebnadzor and the Russian Academy of Medical Sciences were targeted to

³²⁴ Voice of Russia (2009) 'Flu and Acute Respiratory Diseases Decrease in Russia', *Voice of Russia*, 27 November 2009, on the Internet: http://english.ruvr.ru/2009/11/27/2429654.html (retrieved 10 December 2009).

WHO (2008) 'Epidemiology of Crimean-Congo Haemorrhagic Fever Virus: Turkey, Russian Federation, Bulgaria, Greece, Albania, Kosovo', 11 August, World Health Organization Regional Office for Europe, on the Internet:

http://www.euro.who.int/communicablediseases/outbreaks/20080806_1?PrinterFriendly=1& (retrieved 10 March 2009).

³²⁶ Platonov, Alexander et al. (2008) 'Epidemiology of West Nile Infection in Volgograd, Russia, in Relation to Climate Change and Mosquito (Diptera: Culicidae) Bionomics', *Parasitology Research*, Vol. 103, Supplement 1 (23 November), on the Internet:

http://www.springerlink.com/content/c866061257126677/ (retrieved 10 March 2009).

327 ProMED-mail (2010) 'Haemorrhagic Fever with Renal Syndrome – Russia', 4 March, on the Internet'

http://www.promedmail.org/pls/otn/f?p=2400:1001:16484589277234::NO::F2400_P1001_BAC K_PAGE,F2400_P1001_PUB_MAIL_ID:1000,81616 (retrieved 10 March 2010).

Russian Federation (2008) Resolution of the Government of the Russian Federation from 27 October 2008 No. 791, 'On the Federal Target Program The National System of Chemical and Biological Security of the Russian Federation (2009–2013 years)', on the Internet: http://www.garant.ru/prime/20081106/2066728.htm (retrieved 11 March 2009).

Wistar Institute (2006) 'The Wistar Institute Licenses Rubella Vaccine Seed Stock to Microgen of Russia', *Medical News Today*, 7 January, on the Internet: http://www.medicalnewstoday.com/medicalnews.php?newsid=35859 (retrieved 4 May 2007).

play important roles for R&D. The national priority projects in the health sector included the prevention of HIV and hepatitis B and C, the detection and treatment of HIV, and supplementary immunization of the population in addition to influenza immunization. An HIV vaccine was under development by Vector scientists in an International Science and Technology Centre project 2007. 330 An example of a joint EU-Russian project was one that would develop a rapid plantbased system to produce and assess the capacity of different proteins to act as vaccines against important diseases of livestock such as avian influenza and blue tongue. The project was funded under the EU Seventh Framework Programme (FP7) (Cooperation; Theme: Food, agriculture and fisheries, biotechnology).³³¹

The Russian Government also improved the public health system, strengthening its regional policies and programmes to achieve a more robust public health system by:

- 1. focusing on surveillance, laboratory diagnostics, and the development of countermeasures (e.g. drugs, vaccines) capable of addressing diseases in the broadest sense;
- 2. improving capabilities to detect and diagnose new, re-emerging, and antibiotic-resistant pathogens in both rural and urban settings and upgrading communication systems to provide timely and accurate information;
- 3. enhancing disease surveillance, encompassing affected species of significance;
- 4. monitoring food and water supplies for safety and potability;
- 5. supporting well-focused research projects that strengthen the base of fundamental scientific knowledge;
- 6. strengthening programmes to facilitate the commercialization of scientific findings within a regulatory framework that supports public health and the protection of agriculture;
- 7. developing an improved understanding of the relationships between infectious agents and important chronic diseases, a priority of growing international interest;
- 8. supporting the emergence of a strong biotechnology sector that enhances efforts to combat infectious diseases affecting the Russian population;

331 European Biotechnology News (2009) 'European–Russian Cooperation to Produce Novel Animal Vaccines from Plants', *European Biotechnology News*, 4 February 2009.

³³⁰ ISTC, International Science and Technology Centre homepage, on the Internet: http://www.istc.ru/istc/sc.nsf/stories/tomato-vaccine.htm (retrieved 8 May 2007).

- 9. developing and implementing effective security procedures at the hundreds of facilities that can propagate, store, or distribute pathogens which, if diverted, could be used for bioterrorism; an important initial step is to conduct a careful nationwide inventorying of the many collections in Russia and consolidate collections where appropriate;
- 10. promoting broad transparency of Russian research and diseaseprevention and control activities involving dangerous pathogens in order to reduce international apprehensions regarding the possible misuse of Russian research or unauthorized diversion of infectious agents, with comparable transparency also expected in other countries; and
- 11. recruiting, training and retaining an expanded cadre of biomedical scientists, medical doctors, veterinarians, plant pathologists, epidemiologists, and other relevant specialists who are equipped with modern technology and positioned to deal with infectious disease threats.³³²

³³² 'Biotech in Russian Post Crises Economy: Visionary plans or a call of duty', *MGIMO*, 1 December 2009, on the Internet: http://www.mgimo.ru/news/experts/document128432.phtml

(retrieved 10 March 2010).

12 Developments in the Russian Pharmaceuticals Industry

During the Soviet era domestic production covered a substantial portion of pharmaceuticals consumption, with the balance made up by imports from Central European countries. Before 1991, the domestic pharmaceuticals industry produced more than 3000 different preparations and 70 per cent of all synthetic drugs, 85 per cent of all antibiotics, 90 per cent of all vitamins and 100 per cent of all biological immuno-preparations consumed in Russia, using mostly domestic raw materials. Since then, antibiotic production has declined sharply and almost ceased in Russia.³³³ The number of domestically produced drugs fell rapidly in the early 1990s. According to the Institute of State Drug Control there were a total of 32 foreign pharmaceuticals companies from 18 countries active in Russia in 1994 and the number rose to 168 foreign companies from 30 countries in 1999. ³³⁴

The break-up of the Soviet Union caused massive disruption to pharmaceuticals production and the industry that remained within the Russian Federation was largely outdated and poorly maintained. With the rapid transition to a market economy, a number of factors combined to make pharmaceuticals production unprofitable, resulting in a drastic decline in production levels. This involved a sharp increase in the price of raw materials, energy and transport, disruption to the cooperative links between production plants and R&D institutes, severe resource constraints, lack of customs barriers on imported substances, increased competition from imported products, and tax privileges for suppliers from abroad. Substance production within the Russian Federation dropped by 60 per cent in the period up to 1997 and local producers, furthermore, increased their prices dramatically, making them uncompetitive compared to imports. This resulted in the volume of production dropping by a factor of five.

In 1997, there were 120 pharmaceuticals factories and 21 plants involved in substance production, as well as 42 research institutes synthesizing immuno-biological preparations. These were working at 25–50 per cent of their capacity, with 70–90 per cent of the equipment nearing the end of its useful life. At the

³³³ Civil G8 (2006) 'Critical Situation in Russian Medical Industry', Civil G8 – 2006, on the Internet: http://en.civilg8.ru/priority/infection/1623.php (retrieved 3 April 2008).

³³⁴ Pravda (2004) 'Mafia Dominates Russian Pharmaceutical Industry', *Pravda* online, 29 November 2004, on the Internet: http://www.garant.ru/iconf/report/83.htm (retrieved 26 February 2008); and Semenko, I. (2000) 'Drug Industry Shows Uneven Development, Independent Press', *Moscow Times*, 4 March 2000.

³³⁵ Ministry of Economy and Ministry of Health (1998) 'The State of Production and Realization of Medicines in the Russian Federation in 1998', Report issued by the Ministry of Economy and the Ministry of Health.

same time, the volume of imported substances and finished pharmaceutical products was increasing dramatically. By 1997, 93 per cent of producers were relying on imported substances, with the proportion of imported products rising to 65 per cent in the late 1990s. The number of drugs registered for sale increased from 5000 in 1992 to 12 000 in 1998. In 2009, the State Register contained 140 000 products, many of which were new to doctors. Such extreme liberalization of pharmaceutical products made control impossible. By comparison, most West European countries managed well, with a few thousand products on their drug formularies. Many of the pharmaceuticals sold in the Russian Federation in 2009 had no proven pharmacological value.

In 1998, Russia adopted a government programme called Development of Medicinal Industry in 1998–2000 and up to 2005. The aim was to organize domestic facilities for the production of new substances in order to allow 70 per cent of the country's pharmaceuticals needs to be covered by domestic production. However, this programme, like many similar ones, remained unfunded through the federal budget. One positive step was the approval of the Russian GMP standard in 1998, with a provision it must be implemented by manufacturers within five years. After this period non-compliant producers should in principle be closed down. In spite of this very few manufacturers had taken substantial steps toward implementation in 2009. 336

After a decline around 2000, when many foreign investors froze their assets, several large Russian investors, including Bryntsalov and Abromovitch, began to buy into the Russian pharmaceuticals industry.³³⁷ In 2001 biotechnological products for the Russian pharmaceuticals market were worth \$580 million, with Russian companies accounting for 25–38 per cent of the market.³³⁸ Imports of biopharmaceutical products to Russia in 2004 were estimated to have a value of \$495 million, of which 28.6 per cent was accounted for by insulin, 28 per cent by hormones, 13 per cent by vaccines and 11.1 per cent by serums.³³⁹ The number of Western players in the Russian market rose sharply after 2004. The outdated infrastructure and Russia's failure to fulfil the requirements of international standards like GMP were still discouraging European companies from investing

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³³⁶ WHO (2002) 'Pharmaceuticals, Country Profiles', on the Internet: http://www.euro.who.int/pharmaceuticals/Topics/Overview/20020414_7 (retrieved 27 October 2009)

³³⁷ Pravda (2004) 'Mafia Dominates Russian Pharmaceutical Industry', *Pravda* online, 29 November 2004, on the Internet: http://www.garant.ru/iconf/report/83.htm (retrieved 26 February 2008); and Semenko, I. (2000) 'Drug Industry Shows Uneven Development, Independent Press', *Moscow Times*, 4 March 2000.

Borodina, E. (2002), 'Biotechnology Market in the Russian Far East', *BISNIS*, Vladivostok, July.
 Abercade Consulting (2005) 'Biotechnology: Review of the market in 2004', on the Internet: http://www.abercade (retrieved 26 January 2008).

in the Russian pharmaceuticals industry. However, Russia remained an attractive location for clinical trials. 341

The low level of domestic production of pharmaceuticals can thus be traced back to the allocation of resources during the Soviet era with central planning. Furthermore, R&D in the pharmaceuticals sector targeted only states in the former Eastern bloc. During the Soviet era, the domestic pharmaceuticals market in the Soviet Union was dominated by companies from Poland, Hungary and the former Yugoslavia. They continued their activities in Russia after the collapse of the Soviet Union. The domestic industry during the Soviet period focused on the production of separate active medical substances (raw materials for medicines) such as antibiotics and vitamins, while the production of ready-to-use drugs for the Soviet bloc countries was organized at plants based in Hungary, Poland and the Czech Republic. 342

It has been estimated that in 2006 the Russian pharmaceuticals industry was 15 or even 20 years behind that of the developed world. Most Russian manufacturers were still producing pharmaceutical products, mainly generics, whose patents had expired 15–20 years before. There were also a number of domestic producers that manufacture identical products.

Russia represents approximately 1 per cent of the global market for pharmaceuticals, including biopharmaceutical products. Less than one-third of expenditure on pharmaceuticals was financed by the Russian Government and health care expenditures accounted for about 2.2 per cent of GDP 2005. There was little link between choice of areas for research and domestic pharmaceuticals sales: for example, relatively large resources were spent on the development of vaccines, although they represent only a very small part of the market. In 2005 the ten largest pharmaceuticals companies in Russia spent \$12 million on R&D while the top 10 companies in the world spent \$41 billion for the same purpose. Around 100 Russian companies provided 90 per cent of the

³⁴⁰ Langley, Andrew (2006) 'Russia's Pharmaceutical Market Gains Appeal', Wall Street Journal On-line, 25 September 2006, on the Internet:

http://online.wsj.com/article/SB115914471238872669.html?mod=health_home_stories (retrieved 8 May 2007).

³⁴¹ On the Internet: http://www.frost.com/prod/servlet/report-brochure.pag?id=4H80-01-00-00-00 (retrieved 23 February 2009).

³⁴² Business Wire (2006) 'Russian Pharmaceutical Industry Trails West', *Business Wire*, 18 May 2006, on the Internet:

http://findarticles.com/p/articles/mi_m0EIN/is_2006_May_18/ai_n26867043/ (retrieved 26 October 2009).

NAS (2006) Biological Science and Biotechnology in Russia, Controlling Diseases and Enhancing Security (Washington, DC, National Research Council of the National Academies, NAS Press), p. 49.

Farmatsevtichesky Gazette (2009) 'The Main Directions of Development of Pharmaceutical and Biotechnology Industries', *Farmatsevtichesky Gazette*, 7 November 2009.

Russian-manufactured pharmaceuticals sold on the domestic market. Then there were around 600 companies that produced the remaining 10 per cent of the whole volume for the Russian market, but these were not well controlled. The number of companies is too high; around 40 would be a realistic number.³⁴⁵

	Table 9. The Russian Pharmaceuticals Market and Estimated Growth Rate, in % per year ³⁴⁶				
Year	Pharmaceutical market (\$ billion)	Growth %	Part financed by DLO (\$ billion)		
2001	2.5				
2004	6.4				
2005	8.4	35	1.4		
2006	10.8	30	1.0		
2007	12.6	16	1.3		
2008	16.9	20	2.5		
2009	16.6	13	2.8		
2010	17.2				
2011	18.7				
2012	20.0				
2013	31.6				

In the early stages of decentralization, several regions compensated for the lack of federal legislation by passing their own pharmaceuticals legislation. This practice gradually disappeared and a clear division of responsibilities between

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³⁴⁵ Civil G8 (2006) 'Critical Situation in Russian Medical Industry', Civil G8 – 2006, on the Internet: http://en.civilg8.ru/priority/infection/1623.php (retrieved 3 April 2008).

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³⁴⁶ Farmatsevticheskii Vestnik (2009) 'Russia's Pharmaceutical Market During and After the Crisis', Farmatsevticheskii Vestnik, 14 July 2009, on the Internet: http://www.pharmvestnik.ru/ (retrieved 12 October 2009); Bairamashvili and Rabinovich (2007) 'Russia through the prism', pp. 801-17; DSM Group, Moscow, 21 August 2008, on the Internet http://www.biopharmanalytica.com/ (retrieved 19 February 2009); Euromonitor International's OTC Healthcare in Russia, Executive Summary, March 2007; Biopharmanalytica, on the Internet: http://www.biopharmanalytica.com/index.asp (retrieved 26 February 2008); and Russia Pharmaceuticals and Health Care Report Q4 2009, Companiesandmarkets.com, 8 October 2009, on the Internet: http://www.companiesandmarkets.com/Summary-Market-Report/russia-pharmaceuticals-and-healthcare-report-q4-2009-161766.asp (retrieved 27 February 2009).

the federal and regional authorities was established. Federal responsibilities were clearly defined by the federal drug law, which covered the entire Russian Federation, while a large number of federal-level regulations and decrees were proposed as guidelines and recommendations for further adjustments by the regions themselves.³⁴⁷

The Russian pharmaceuticals market had grewn by 10–12 per cent per year from 2000 until 2008. This was in fact not so impressive since it followed the growth in real incomes, which averaged around 11–12 per cent per year. Table 9 shows the growth rate for the Russian pharmaceuticals market and the extent to which the governmental subsidy system, the DLO (Federal Beneficiary Drug Provision Programme – Dopolnitel'noe Lekarstvennoe Obespechenie), is responsible for of the total Russian market. The growth rate for the pharmaceuticals market made Russia the eleventh-largest pharmaceuticals market in the world. The growth rate for the pharmaceuticals market made Russia the eleventh-largest pharmaceuticals market in the world.

Russia had from 2000 until 2009 remained heavily dependent on imports and domestic production accounted for about 30 per cent of the market value. In general the share of local producers in the market was growing, but this change was going very slowly. Even if Russian producers were to become very active in R&D, it would take a long time before new drugs reached the market. Competition from foreign countries and especially Western countries was intense, and foreign products were often perceived in Russia as more effective and of higher quality. 350

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³⁴⁷ WHO (2002) 'Pharmaceuticals, Country Profiles'.

Trusted Sources (2007) 'Russian Pharma: From distribution to biotech', *Trusted Sources*, 7 September, on the Internet: http://www.trustedsources.co.uk (retrieved 25 August 2009).

DSM Group (2008) Moscow, 21 August, on the Internet: http://www.biopharmanalytica.com/ (retrieved 19 February 2009).

NAS (2006) Biological Science and Biotechnology in Russia, Controlling Diseases and Enhancing Security (Washington, DC, National Research Council of the National Academies, NAS Press), p. 47.

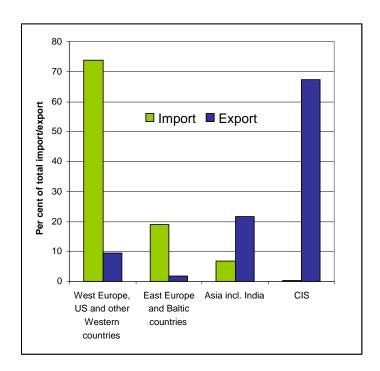


Figure 3. Imports and exports of pharmaceutical products until October 2006, as percentages of total imports or exports (compiled by Kristina Westerdahl, FOI). ³⁵¹

Imports of pharmaceuticals increased by 45 per cent from 2005 to 2006, 352 of these 71 per cent came from Western countries. 353 One reason for the higher imports was the increased state subsidies in the public purchase of medicines. In 2006, the share of imports was 69 per cent and it remained at that level until 2009. Of market sales in 2008, 70 per cent were commercial, 17 per cent federal or government and 13 per cent hospital sales. Imports and exports of pharmaceutical products are illustrated in Figure 3.

355 Trusted Sources (2007) 'Russian Pharma'.

Data, up to and including October 2006, from TsMI Farmekspert (2006), 'Rossiiskii farmatsevticheskii rynok. Itogi oktiabria 2006 g' [Russian Pharmceutical Market. Summary October 2006], *Farmatsevticheskii vestnik*, No. 2, on the Internet: http://www.pharmvestnik.ru/cgi-bin/statya.pl?sid=11732 (retrieved 8 May 2007).

³⁵² Oleynik, E. (2007) 'Import lekarstven 12, on the Internet: http://www.pharmvestnik.ru/cgi-bin/statya.pl?sid=11976 (retrieved 8 May nykh sredstv v Rossiiu' [Imports of Medical Media in Russia], *Farmatsevticheskii vestnik*, No. 2007).

³⁵³ Farmatsevticheskii Vestnik (2006) 'Rossiiskii farmatsevticheskii rynok'.

³⁵⁴ Oleynik, E. (2007) 'Import lekarstvennykh sredstv v Rossiiu'.

In 2007, new drugs segments grew at a rapid pace as more than 230 new drug trade names appeared in the Russian pharmaceuticals market. 356 The market was forecast to continue to grow rapidly. Drug manufacturers were heavily dependent on affluent Russians who could pay cash for some of the more popular drugs from the West, such as Pfizer's sexual dysfunction drug Viagra, Roche's antiviral Tamiflu, Sanofi's anti-clotting drug Plavix, and Novartis' leukaemia treatment Gleevec.³⁵⁷ PharmStandard (Moscow) was the leading domestic pharmaceuticals company in Russia in terms of sales in 2009.³⁵⁸ In 2009, there were approximately 350 Russian pharmaceuticals companies, which accounted for 20 per cent of the market in terms of value. In 2009, the leading pharmaceuticals companies in Russia (indigenous or foreign) were, by value of sales and part of market, the French Sanofi-Aventis (4.2 per cent), Novartis (3.8 per cent), the Russian PharmStandard OOO (3.5 per cent), F.Hoffmann-la Roche Ltd (3.4 per cent), followed by Bayer Schering Pharma AG (3.1 per cent). 360 Russian production still consisted mainly of outdated drugs; modern high-tech products accounted for around 10 per cent. The pharmaceuticals market in Russia also experienced severe losses during 2009, due to the financial crisis – around 9 per cent (equivalent to the fall in GDP by 9 per cent in 2009) after eight years of annual growth. ³⁶¹ The forecast growth rates are shown in Table 9.

Table 10 shows the largest pharmaceuticals companies for the import of drugs to Russia in 2006. In 2008 foreign companies stated that the Russian legal framework remained too complicated for drug manufacturing. They were frustrated by dealing with the Russian regulators who approved the drugs for safety for the domestic market. Russia's drug approval process was hampered by 'arbitrary' fees and 'unnecessary' requirements for re-registering products every five years, as well as demands for 'duplicate' drug tests. There were excessive

356 China CCM (2008) 'Russian Pharma Sector Analysis', on the Internet: http://www.chinaccm.com/4S/4S40/4S4001/news/20090220/115129.asp (retrieved 10 May 2009).

³⁵⁸ Pharmaceutical Technology (2009) 'Standard Setting Bodies Engage Russia', *Pharmaceutical Technology*, Vol. 33, Issue 10, 2 October 2009, on the Internet: http://pharmtech.findpharma.com/pharmtech/Article/Standard-Setting-Bodies-Engage-

Russia/ArticleStandard/Article/detail/632991 (retrieved 12 October 2009).

Russian Federation (2009) 'Vladimir Putin on the Development of a Strategy for the Pharmaceutical Industry', Government of the Russian Federation, 19 October 2009, on the Internet: http://premier.gov.ru/eng/pda/events/3816.html (retrieved 27 October 2009).

360 'Russian pharma market showed growth of 18%, despite the global economic crisis' The Pharma Letter, 16 march 2010, on the internet: http://www.thepharmaletter.com/file/a2233c0fe046fb95a8432635e9760bc8/russian-pharma-

³⁵⁷ Ibid.

market-showed-growth-of-18-despite-the-global-economic-crisis.html (retrieved 7 April 2010)

Russia Pharmaceuticals & Healthcare Report 2008, Business Monitor International, on the Internet: http://www.businessmonitor.com/pharma/russia.html (retrieved 26 February 2008); and on the Internet: http://www.chinaccm.com/4S/4S40/4S4001/news/20090220/115129.asp (retrieved 5 April 2009).

rules and administrative procedures. Russia's regulatory system needed to become more in-line with European standards, and its DLO system improved.³⁶² The authority responsible for monitoring health, Roszdravnadzor, initiated a plan which stated that all pharmaceuticals companies had to be certified as meeting the requirements of the international GMP standard by 2010.

Table 10. The Largest Pharmaceuticals Companies for the Import of Drugs to Russia, 2006³⁶³

Company	% of the market	% increase in imports 2005
Sanofi-Aventis	6.51	10
Novartis	5.22	29
Janssen-Clag	4.48	157
Servier	4.33	78
Berlin-Chemie/Menari	4.04	10
Solvay Pharma	3.25	112
Richter Gedeon	3.14	24
Roche	2.99	69
Sandoz	2.95	33
Schering AG	2.93	133
Pfizer	2.67	6
GlaxoSmithKline	2.66	43
Novo Nordisk	2.47	-2
AstraZenica	2.42	73
Abbott Laboratories	2.40	311
(Source Pharmexpert)		

The Russian Government established a pharmaceuticals holding company called Russian Pharmaceutical Technologies (RFT). Some of the biggest pharma

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http://money.cnn.com/2008/04/02/news/companies/pharma_russia/index.htm?postversion=2008040412 (retrieved 10 April 2008).

³⁶² CNNMoney.com, 4 April 2008, on the Internet:

³⁶³ Global Insight (2007) 'Drug Imports Up 45% in Volume Terms as Sanofi-Aventis Remain Top Big-pharma Operator in Russia', *Global Insight*, 30 April, on the Internet: http://www.globalinsight.com/SDA/SDADetail9106.htm (retrieved 26 February 2008).

players, including Sanofi-Aventis (France), Pfizer (U.S.) and Novartis (Switzerland), have held preliminary negotiations to see if they should invest in a new holding aimed at boosting the presence of domestic drug companies in the Russian pharmaceutical market. Russian Pharmaceutical Technologies (RFT) was officially launched in December 2007, and will comprise five state-owned drug-makers and nine research institutes. Foreign pharmaceuticals producers were to be allowed to buy out almost 50 per cent of the new venture. 365 One way of strengthening this venture was to introduce original, Russian-produced medication for curing cardiovascular diseases, tuberculosis, diabetes, blood diseases and so on. 366 The controlling stake of RFT was to remain governmentowned. The combined company was expected to have an initial market value of \$250–300 million, and the government said that it expected this to increase to as much as \$1.5–2 billion by 2011. Russia's health authorities have been searching for ways to boost the presence of domestic drug companies in the country's pharmaceuticals markets for a long period of time, but local firms tended to be small and the market remained fragmented. By merging the research, development and production capacities of several companies, the hope was that the pooled resources would allow for a greater number of treatments to be manufactured at lower cost.367

One problem that Russia continued to struggle with was the existence of unauthorized copies of drugs, mostly antibiotics (estimated to cover 10 per cent of the market). It was estimated that 70 per cent of them were produced in Russia and often based on imported intermediate products for manufacturing. In 2006, it was estimated that counterfeit drugs production in Russia was worth \$300 million per year. Sales of counterfeit medicines remained high in terms of value, although the volume seemed to be decreasing. Many of these products continued to be sold through private pharmacies. The world market, according to WHO for counterfeit drugs was estimated to be worth \$32 billion in 2003.

³⁶⁴ Bairamashvili and Rabinovich (2007) 'Russia through the Prism', p. 815.

³⁶⁵ It will include the Moskhimfarmpreparaty Moscow factory, the Kaliningrad pharmaceuticals factory, the R&D institute for medical industry, the All-Russia Research Centre for the Safety of Biologically Active Elements, the R&D Institute for Vitamins, R&D for biosyntheses of protein substances, Belgorod R&D for medical industry technologies, and 55.5 per cent of the Altai pharmaceuticals factory Vostokvit.

³⁶⁶ Kommersant (2007) 'Pharmaceutical Holding to Get Foreign Aid', *Kommersant*, 1 March.
³⁶⁷ Global Insight (2007) 'Foreign Drug Firms Offered Chance to Buy Stake in New Russian Pharma Conglomerate', on the Internet:

http://www.ihsglobalinsight.com/SDA/SDADetail8593.htm (retrieved 12 October 2009).
³⁶⁸ Parfitt, Tom (2006) 'Russia Cracks Down on Counterfeit Drugs', *The Lancet*, Vol. 368 (28 October–3 November), pp. 1481-82.

New York Times (2006) 'Drug Piracy: A wave of counterfeit medicines washes over Russia', New York Times, 5 September 2006, on the Internet: http://www.nytimes.com/2006/09/05/business/worldbusiness/05fake.html (retrieved 9 September 2009)

Russia's pharmaceuticals sector retained some special characteristics, and one result of this was that total spending on pharmaceuticals relative to GDP remained well below the OECD average, as this was not a government priority. The importers who dominated the Russian market, given the weakness of domestic producers, did not treat this market as a top priority. This may change with the lessons learned from the government's first serious attempt to boost pensioners' access to medicines (as part of the DLO programme) and attempts to promote domestic biotechnology R&D in order to discover new drugs. While sales of pharmaceuticals in Russia increased by nearly one-third in 2006, there was a slowdown in growth in 2007 largely due to the funding of the Russian Federation's drug reimbursement programme.

The DLO programme has become one of the most important factors driving growth in the Russian pharmaceuticals market. It was introduced in 2005 to compensate for the cancellation of certain social welfare benefits. Under the programme, over 14 million Russians (mostly retired people and war veterans) were provided with medicines subsidized by the federal budget. The programme stated that expensive drugs could be purchased by the state, to be distributed free to priority groups.³⁷⁰ Pharmaceuticals companies provided drugs to pharmacies through selected distributors and the government later reimbursed the companies. However, a crisis arose with the financing of the system when insufficient funding was allocated in 2005. Furthermore, corruption was revealed and there were calls for the health minister to resign. 371 Originally \$1.7 billion was set aside, which was then reduced by 41 per cent in 2006 when the population could choose between different rights, including free medicine or 513 roubles each per month, and about 50 per cent chose the latter. This led to budget reductions. For 2007, the budget was increased to \$1.3 billion.³⁷² In 2005, sales of pharmaceuticals available under the DLO contributed as much as 20 per cent of the total market growth (of 35 per cent) and a total of 154 million beneficiary prescriptions were written in 2005. 373

It was hoped that the DLO programme would reduce the amounts of imported drugs, but it remained at around 70 per cent of the market value in 2007.³⁷⁴ In

³⁷² Parfitt (2007) 'Russia's Prescription Drugs Crisis'; and *The Russia Pharmaceuticals & Healthcare Report 2008*, Business Monitor International, on the Internet:

³⁷⁰ Kommersant (2007) '2/3 of Russia's Pharmaceutical Enterprises Not In Line With Global Demands', *Kommersant*, 23 March, on the Internet: http://www.kommersant.com/p-10379/r 530/pharmaceutical quality/ (retrieved 13 May 2007).

Parfitt (2007) 'Russia's Prescription Drugs Crisis'.

 http://www.businessmonitor.com/pharma/russia.html (retrieved 26 February 2008).
 pharma/russia.html (retrieved 26 February 2008).
 Pharma Poland News (2006) 'Russian Pharmaceutical Market – Overview', *Pharma Poland News*, PMR Publications, July, on the Internet:

http://www.pharmexcil.com/V1/docs/RussianPharmaceuticalmarketoverview.pdf (retrieved 19 February 2009).

Trusted Sources (2007) 'Russian Pharma'.

2009 around 80 per cent of DLO funds were spent on imported pharmaceuticals. Prime Minister Putin has stated that the policy for the state to purchase medicines needs to be overhauled by replacing DLO with a compulsory health insurance and provide free or low-cost prescriptions drugs to all Russians. In the new system only Russian produced drugs will be subsidized. The health sector will be reformed in 2010. Russian-manufactured medicines purchased using government money must, according to Putin, make up not less than half of the total supply, in terms of value, by 2012 or 2013.

According to Putin, the greatest possible number of medicines should be manufactured in Russia, in particular through licensed production and generics. A list should be developed of the most important and essential medicines and, based on this, domestic manufacture of these should be promoted through targeted research and development at institutes. Putin has further stated that it was taking Russian manufacturers far too long to implement the GMP standards and other international standards, without which the Russian pharmaceuticals industry will never become competitive on the world market. From 2011 the government planned to stop purchases of products that did not comply with the standards for production. The development strategy for the pharmaceuticals industry, if implemented, would increase the share of Russianmanufactured medicines from 19 per cent to 50 per cent in terms of value. Innovative medicines would make up 60 per cent or more of the entire output and 85 per cent of important and essential medicines would be manufactured in Russia.³⁷⁶ Putin has further promised that the government will allocate 700 million roubles to subsidize interest on loans for pharmaceuticals companies, which was intended to help them modernize production. President Medvedev also commented on the situation for the pharmaceuticals industry in his address to the Duma in November 2009 (see Appendix 2):

The modernisation area of top importance for our people is developing medical technology, medical equipment, and the pharmaceuticals industry. We will provide people with quality and affordable medicines and also the latest technology for preventing and treating diseases, especially the diseases that are the biggest causes of sickness and death in our country. We have already drawn up a list of strategically important medicines that should be produced here in Russia. This includes the most expensive medicines, in particular medicines for treating cardiovascular diseases and cancer. We will need to produce more than 50 such medicines so that everyone who needs them will be able to receive timely treatment. Also we will soon dramatically increase production of our own medicines for

³⁷⁵ Russia World Pharmaceutical Market (2010) 'The Pharmaceutical Market: Russia, opportunities and challenges' Report Epicom, 27 January.

³⁷⁶ Russian Federation (2009) 'Vladimir Putin on the Development of a Strategy for the Pharmaceutical Industry'.

treating the most common diseases such as colds and flu. I think that Russian companies have the ability to produce medicines and technology that would find demand on the global market. For this we need to work more actively on developing partnerships with leading foreign developers and producers, who can contribute to organising advanced medical research in Russia itself. We will also use the public procurement mechanism to encourage domestic production of medicines and technology. Within five years, Russian-made medicines should account for at least a quarter of the medicines market here and for more than half of the market by 2020. 3777

Prime Minister Putin considered the establishment of a national pharmaceuticals industry as a national security issue. In line with, this the Development Strategy for the Pharmaceutical Industry until 2020 was prepared by the Ministry of Education and Science and first presented in the Duma in June 2008. The aim was for the country to restore domestic production of drugs that were in high demand within ten or twelve years. The Strategy included proposals to create a list of priority projects for the development of domestic pharmaceuticals production in order to make investment more attractive and to improve activity in the pharmaceuticals industry. It also called for improvement in the drugs their harmonization with international requirements. regulations and Furthermore, it pointed to the need to establish uniform access rules for domestic and foreign manufacturers in the pharmaceuticals market. At the same time, the domestic market for medicines needed to be protected, exports needed to be promoted, and the pharmaceuticals industry needed to implement the contemporary national standards of production and quality control.

The Strategy for the Pharmaceuticals Industry Development up to 2020 was then approved in October 2009. It was aimed at increasing the competitiveness of the domestic pharmaceuticals industry. It envisaged the government supporting local pharmaceuticals producers by covering their costs for R&D to develop innovative drugs. Total financing of the programme for 2009–2020 was 177 620 million roubles (\$6 billion), of which 100 billion roubles is to be spent on developing domestic medicines and reducing dependence on imports.³⁷⁹ The view of the government was that the industry needed integrated structures linking

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³⁷⁷ Presidential Address to the Federal Assembly of the Russian Federation, The Kremlin, Moscow, 12 November 2009, on the Internet:

http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009).

Journal of Commercial Biotechnology (2008) 'The Establishment of a National Pharmaceutical Industry – An issue of national security', *Journal of Commercial Biotechnology*, 9 June 2008.

³⁷⁹ Global Trade Alert (2010) 'Russia: Strategy of pharmaceutical industry developed 2020', Measure 1135 (February), Global Trade Alert, on the Internet: http://www.globaltradealert.org/measure/russia-strategypharmaceutical-industry-development-2020 (retrieved 8 March 2010).

research and development with manufacture.³⁸⁰ The strategy includes the following aspects:³⁸¹

- Increasing the share of domestic products in the domestic market for pharmaceuticals to 50 per cent (in value terms) by 2020;
- At least 80 per cent must be under patent protection;
- Changing the selection of medications sold in Russia and increasing the number of innovative products by up to 60 per cent in value terms;
- Increasing exports of pharmaceutical products by eight times compared to 2008;
- Ensuring the safety of medicines in Russia in compliance with the list of strategic medications and vaccines; and
- Stimulating the establishment of companies and the production of pharmaceutical substances in Russia in volumes large enough for companies to produce 50 per cent of finished pharmaceuticals for the domestic market (in money terms), including no less than 85 per cent by products named on the list of strategic medications. This should be achieved through:
 - 1. Attracting companies to locate their high-technology production of medicines in Russia:
 - 2. Stimulating the establishment of production of high-technology chemical and biochemical substances in Russia;
 - 3. Encouraging the obligatory switch by domestic pharmaceuticals manufacturers to working according to GMP standards by 2011;
 - 4. Encouraging the development and production of generic and innovative medicines;
 - 5. Developing new educational programmes and modifying existing ones in order to enhance staff qualification and provide the pharmaceuticals industry with new specialists; and
 - 6. Ensuring the safety of medicines in the Russian Federation.

³⁸¹ Russian Ministry of Industry and Trade, The Strategy of the Pharmaceutical Industry Development up to 2020, Decree No. 965, 23 October 2009.

³⁸⁰ Russian Federation (2009) 'Vladimir Putin on the Development of a Strategy for the Pharmaceutical Industry'.

The programme is to be implemented in three stages:

- 1. Attracting high-tech development and production to Russia;
- Developing the domestic pharmaceuticals industry.
 Substituting imported products with locally produced generics.
 Purchasing licences.
 Ensuring that the national pharmaceuticals industry can remain
 - independent; and
- 3. Expansion of national pharmaceuticals producers abroad in foreign markets.

Development of innovative drugs that are analogues to drugs already patented.

Development of innovative drugs to be patented.

Some experts are not sure if the aims of this strategy really are realistic. The time set for achieving its goals was also probably too short. Some Russian pharmaceuticals firms say that the new government legislation is not the right prescription for the market and could increase the prices of pharmaceuticals, despite government price controls. It can also be noted that in 2009 prices increased by 40 per cent, partly as a result of changes in exchange rates. The pharmaceuticals industry can be said to have been outside proper control since the year 2000, according to the deputy chairman of the State Duma Health Committee. The situation in 2009 was far from satisfactory, according to Prime Minister Putin. Foreign medicines were often sold for prices higher than in any other country, which is hard to justify. This Strategy could lead to the creation of a new scientific basis and could govern the whole innovation cycle in Russian pharmaceuticals companies, but this would require major financial investments. The strategy could be sufficiently according to the creation of a new scientific basis and could govern the whole innovation cycle in Russian pharmaceuticals companies, but this would require major financial investments.

In August 2009, President Medvedev criticized the dearth of innovation in the pharmaceuticals industry, which relied too much on manufacturing generic drugs: 'By and large, our industry continues to make the same outdated products and, as a rule, imported generics from substances bought abroad. There is practically no work to create original medicines and technologies.' According to Medvedev, the government wanted private companies to take the lead in modernizing the industry. One such project, on which high hopes were pinned, was Generium, a Russian joint venture of the companies Lekko and

383 Russian Federation (2009) 'Vladimir Putin on the Development of a Strategy for the Pharmaceutical Industry'.

³⁸² Sulimina, Anna (2010) 'Russia's Pharma Braced for Shake-up', *Moscow News*, 23 February, on the Internet: http://www.mn.ru/feature/20100223/55414832.html (retrieved 8 March 2010).

³⁸⁴ Russian Business Newspaper (2008) 'The Range of Drugs in the Russian Chemist Becomes Smaller', *Russian Business Newspaper*, 30 December 2008.

PharmStandard established in the hope of attracting Russia's best scientists in genetic engineering. 385

Industry Minister Viktor Khristenko also commented in August 2009 that there should be a focus on the production of medicines and equipment to deal with the six major causes of mortality in Russia. Of the 3000 drugs sold in Russia, the list of essential drugs included 650 items of which 248 were not produced in Russia. Among these 103 drugs were essential. The minister outlined five major projects proposed in order to produce more drugs domestically. 386

The forecast growth for 2009- 2014 for the Russian pharmaceutical market after the decline in 2009 was estimated at a compound average growth rate (CAGR)³⁸⁷ of 14 per cent in roubles. The Russian pharmaceutical regulatory environment remained in a flux including reforms of registration procedures and market oversight driven by the Federal Anti-Monopoly Service (FAS). It would also formulate new rules limiting the activity of medical representatives from drug companies. To support and expand the domestic sector under its current Strategy for the Development of the Pharmaceutical Industry, the government approved some 29 projects by local players in the healthcare sector.³⁸⁸

RT Business (2009) 'Pharmaceutical Sector Looks to the Future with More Private Funding', *RT Business*, 31 August, on the Internet: http://russiatoday.com/Business/2009-08-31/pharmaceutical-sector-looks-future.html (retrieved 27 October 2009).

³⁸⁶ ITAR-TASS (2009) 'Khristenko at the Commission Meeting on Modernization and Technological Development of Economy of Russia', *ITAR-TASS*, 31 August 2009.

³⁸⁷ Compound Annual Growth Rate (CAGR) is a business and investing specific term for the smoothed annualized gain of an investment over a given time period. CAGR is widely used, particularly in growth industries.
³⁸⁸ Russian Pharmacoutical and Market and Market

³⁸⁸ Russian Pharmaceuticals and Healthcare Report Q1 2010, Russian Monitor International January 2010, on the Internet: http://www.reportlinker.com/p0172715/Russia-Pharmaceuticals-and-Healthcare-Report-Q1-2010.html (retrieved 7 April 2010).

13 Analyses of Trends in Russian Biotechnology

Russia had a well established R&D and production base in biotechnology before the collapse of the Soviet Union. At that time it had a large number of highly qualified scientists and research institutes involved in biotechnology. After the break-up of the Soviet Union and up to 2009, it was less successful in maintaining this base or using it to develop a modern competitive biotechnology and pharmaceuticals industry. Russia came as number four in the world based on the number of scientific articles published in 1990 and it fell to the eleventh place in the world in 2005. The number of articles published in leading international publications fell by 20 per cent from 1995 to 2005. Many of the most talented scientists in the biotechnology area have gone abroad or gone into other businesses because of funding problems. There have been no coordinated attempts to convince them to return to Russia. In reality, Russia has been unable to tempt scientists who are making a good career abroad, to return. There were also signs of a resurgence of state control over scientific work and international cooperation. The surgence of state control over scientific work and international cooperation.

In 2009 President Medvedev reaffirmed the importance of high-technology development as a key to economic growth, democracy and freedom in Russia. 'The "smarter" our economy will be the higher living standards our citizens will enjoy. This will make our political system and society in general more liberated, just and humane'. 390 The Russian Government has set itself the goal of becoming the fifth leading economy in the world and creating a knowledge-based economy. It was only in 2009 that some positive signs in the latter direction could be noted when it came to creating a national innovation system. There are three areas that the innovation policy is directed at: growing attention to benefits of using forecasts and foresight measures, further development of indirect measures to stimulate innovation and support to the innovation infrastructure. It is positive that more ministries are getting involved in the implementation of the innovation policies, growing attention to monitor and evaluate the policies effects and attempts to create a positive innovation climate. Negative is that a lot of innovation policy initiatives are not followed up by concrete measures, still lacking is inter-governmental coordination and evaluation of the policies effects are still underdeveloped. There seems to still be a lack of serious attentioa and

389 Schiermeier, Quirin (2008) 'Russia's International Research Ties Under Threat', *Nature*, Vol. 45514, September, pp. 6-7.

³⁹⁰ RIA Novosti (2010) 'Medvedev Highlights Key Problems Facing Russia in Article', *RIA Novosti*, 6 March 2010, on the Internet: http://en.rian.ru/russia/20090910/156083558.html.

recognition of the importance of science and it is not seen as really a part of the innovation system by the government.³⁹¹

The National Programme for the Development of Biotechnology in Russia 2006–2015 was followed by the Development Strategy for the Biotechnology Industry in Russia 2010–2020, which were related and quite ambitious. If the Strategy was to be adopted and adequate funding provided, it would give biotechnology in Russia a real boost. It can be questioned, however, whether enough financial resources will be provided in the light of the global financial crisis. The Strategy gives a good picture of the current status of Russian biotechnology and how Russia plans to strengthen it, including the priorities for different areas in biotechnology.

Still lacking in 2009 was a satisfactory mechanism to distinguish high-quality research from that of inferior quality. The funding system for R&D went back to the old system, where the heads of institutes negotiated the allocation of resources instead of basing it on a peer-review system of the scientists' proposals and achievements. The system appeared to benefit mainly institutes in Moscow and St Petersburg. Russia still lagged significantly behind leading industrial countries in the area of biotechnology and was ranked by one source as number 70. The domestic industry was developing slowly and this was coupled with low demand for R&D, which in turn signified low demand for highly qualified specialists. The result has been reduced quality in the educational system and increasing difficulties in recruiting scientists in biotechnology.

A competitive biotech and pharmaceuticals industry has been a priority for Russia for a long time, but getting there seems to be difficult. There has been no lack of various government programmes to promote different aspects of biotechnology or drug development, including the most recent strategies. The contents of these programmes/strategies and their aims were well thought-out in most cases. Whether these programmes really were funded and, if they were, how much of the funding was used for R&D, is difficult to establish.

It has been proposed that the strategic directions in the area of biotechnology for Russia should be (1) biopharmaceuticals and biomedical sciences, (2) genetic

³⁹¹ Dezhina, Irina (2008) 'Russian Science Policy'.

Morozov, Oleg and Raif Vasilov (2008) *Rossiiskaia Gazeta*, Federal issue No. 4572 (25 January 2008). Article by Oleg Morozov (first deputy chairman of the Russian State Duma and chairman of the Board of Trustees of the Yu. A. Ovchynnikov Russian Society of Biotechnologists, and Professor Raif Vasilov, president of the Russian Society of Biotechnologists. The article raises the most pressing issues of state of the art of the Russian biotechnology, makes a comprehensive assessment and outlines the prospects of the development of the bioeconomy in Russia. *Rossiiskaia Gazeta*, Federal issue No. 4572 (25 January), on the Internet: http://www.eurasiabio.org/media/news/page-4/ (retrieved 10 March 2010).

engineering (with the emphasis on agriculture), and (3) bioenergy.³⁹³ The high priority given to developing domestic pharmaceuticals using biotechnology methods will only be realistic in close collaboration with foreign partners. The low percentage of Russian biotechnology products on the world market was considered a national security hazard in Russia since biotechnology was one of the most critical technologies for developments in the 21st century. Biotechnology was included in the so-called critical technologies of importance for defence (Appendix 1). The Ministry of Defence was involved in developing, for example, the National Programme for the Development of Biotechnology in Russia 2006–2015, but it kept its R&D efforts in the biotechnology and biodefence areas separate and under its own strict control. There is very limited information on the Ministry of Defence's priorities for R&D in biotechnology. As in other countries, defence R&D was pursued in those areas of biotechnology that have specific applications for the military, as in the case of sensors for chemical and biological substances or of studies for protection against especially dangerous infectious agents or chemical substances. Developments in medicine and health are now mainly done on the basis of R&D needs within the civilian sector rather than, as before, within the military sector. In Russia, as in other countries, the civilian R&D sector will in the long term be the leading research force, from which innovations and new technologies will be adapted for defence purposes.

The Russian pharmaceuticals market in 2009 was really not as large as one could expect taking into account the size of the population. The Russian market was clearly not a priority for foreign pharmaceuticals companies. Only since 2008 has the Russian Government intensified its efforts to facilitate the development of the domestic pharmaceuticals industry. What is needed if Russia is to become internationally competitive is major foreign investment in R&D and production. Increased trade and exchange in the field of biotechnology is something that unites the EU and Russia, if it takes place in conditions where Russian and EU companies can act as partners on equal terms. If the efforts to rectify the shortcomings of the domestic pharmaceuticals industry result only in licensed production of foreign drugs, this would at least reduce foreign dependence, and give some access to modern production methods and techniques.

It has been noted that in the U.S., revenues from industrial biotechnology for biofuels, enzymes and materials are becoming more important than revenues

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³⁹³ Parliamentary hearings (2009) Working Papers for Development of the Strategy for the Biotechnology Industry.

Leijonhielm, Jan et al. (2002) *Den ryska militärtekniska resursbasen, rysk forskning, kritiska teknologier och vapensystem* [The Russian Military-Technical Resource Base, Russian Research, Critical Technologies and Weapons Systems], Report FOI-R--0618--SE (Stockholm, FOI).

from biopharmaceuticals and transgenic crops. 395 'Green' chemistry based on biological processing is already competing with more traditional synthetic chemistry based on petroleum feedstocks in markets worth many hundreds of billions of dollars worldwide. One reason for this is that the regulatory burdens for these types of products are much less than those for biopharmaceuticals. This could be a factor Russia will consider when it decides its priorities among the different areas of biotechnology. One area that has had strong support from the highest level in Russia was to develop a large-scale industry for producing biofuels like bioethanol. This was a high priority as oil is a limited resource. Russia wants to become a leading nation in this area in order for Europe to become dependent on Russian biofuels in the near future.

There is an innovation system in Russia, but it is still not adequate and the institutional structure is not well adapted to the market. ³⁹⁶ There is a need to develop the entire innovation system, which includes the whole chain from basic molecular biological research, applied research and development, to scaling up of processes, commercial financing and manufacturing, marketing and product distribution. The government has so far failed in its attempts of modernization of the research sector Biotechnology is still one of the areas that are considered to have relatively good prospects for Russia. 397 One of the most important measures will be to create a business-friendly environment to attract foreign investment. Investment should be promoted in areas that are particularly suitable for Russia, such as biofuels. Another important priority should be attracting new young researchers. This could be done by promoting high-quality education in the life sciences and providing incentives for top scientists abroad to come back to Russia. The biotechnology industry should be consolidated, and the establishment of biotechnology centres of excellence encouraged. Furthermore, there is a need to reduce state involvement. Public-private partnerships in this area should also be promoted.

Instead of the approximately 350 domestic companies 2009 that produced drugs in Russia, possibly only 40 are needed, with modern equipment to produce a limited number of effective drugs. Another problem is the supply of high-quality

³⁹⁵ Carlson, Robert (2009) 'The Changing Economics of DNA Synthesis', *Nature Biotechnology*, Vol. 27, No. 12, pp. 1091-4.

President of the Russian Federation (2002) 'Basic Principles of the Russian Federation Policy on the Development of Science and Technology for the Period to 2010 and Beyond', Approved by the President of the Russian Federation, Vladimir Putin, Moscow, 2002, in Glenn E. Schweitzer and Rita S. Guenther (eds) (2005) *Innovating for Profit in Russia: Summary of a workshop* (2005), for the Committee on Innovating for Profit in Russia: Encouraging a Market Pull Approach, Office for Central Europe and Eurasia, National Research Council, Russian Academy of Sciences, by Development, Security, and Cooperation (DSC) National Academies of Sciences (NAS), Washington, D.C'.

⁹⁷ Gokhberg, Leonid (2003) Russia: A new innovation system for the new economy (Moscow, Institute for Statistical Studies and Economics of Knowledge).

medical instruments, which were previously produced in the Soviet Union.³⁹⁸ Biotechnology can actively contribute to improving the poor health of the Russian population in general. The variety of pharmaceutical products manufactured using biotechnology is significantly narrower in Russia than in the global market.

A summary analysis of Russian biotechnology produces a number of conclusions. 399

Russia's advantages:

- The education system is of a fairly good standard and quality;
- Russia is prominent in the theoretical disciplines, including mathematics and information technology;
- Most investments in biotechnology are by private entities; and
- Russians are used to applied research in biotechnology, although in the Soviet Union this was oriented towards military needs.

Russian weaknesses:

- During the 1990s, many researchers ended their research career or left the country. This resulted in a shortage of researchers in the age range 35–45 years and made it difficult to recruit researchers;
- Russia lacks a financial infrastructure surrounding biotechnology and there
 is almost no trade in shares for the biotechnology industry. It is also
 difficult to find investors;
- Many in the Russian industry are unfamiliar with Western-style management of companies in a high-tech industry such as biotechnology;
- Approximately two thirds of the biotechnology market in Russia is dominated by foreign companies. There is fierce foreign competition and lack of implementation of international standards inside Russia;
- Protection of intellectual property rights (IPR) is weak; and
- The legal system and the bureaucracy are complex, and there is a long distance between academic R & D and industrial applications.

Despite the weaknesses in the Russian biotechnology, however, there are specific areas where there is a deep and broad knowledge base that could favour the development of an internationally viable biotechnology industry. To prioritize

http://en.civilg8.ru/priority/infection/1623.php (retrieved 3 April 2008).

³⁹⁸ Civil G8 (2006) 'Critical Situation in Russian Medical Industry', Civil G8–2006 (Civil society on the way to the G8 - 2007 summit), on the Internet:

³⁹⁹ Kudryashev, Mikhail (2007) 'SWOT-view on biotechnology in Russia', *Journal of Biotechnology*, Vol. 2, p. 784; and Louët, S. (2005) 'Dmitriy Morosov', *Nature Biotechnology*, Vol. 23, No. 12, on the Internet: http://www.nptemp.ru/files/photo/prod1_docs/227.pdf (retrieved 7 May 2007).

certain areas would require a more extensive analysis than has been made so far of the developments in biotechnology, the research that is of international standing and the potential for commercializing the results. This would in turn require, as mentioned earlier, that the regulatory, legislative and economic conditions for foreign investment are promoted and that the market is kept open for competition on equal terms. Biotechnology was listed as a critical technology in 2006 by the Russian Government and it was mentioned in the list of priorities in the Concept of Long-Term Socio-Economic Development in Russia to 2020, along with nanotechnology and information technology. The ambitions of the government are set very high in that by 2020 Russia should become the fifth leading economy in the world, which is not very realistic looking at the difficulties it has had in promoting a competitive biotechnology industry or a domestic pharmaceuticals industry. This study indicates that it is proving difficult for Russia to reach the goal of becoming internationally competitive in the biotechnology area, despite its high ambitions. Russian pharmaceuticals producers have limited research of their own and the link between industry and academia must be improved.

There are positive developments, like the establishment of clusters of organizations such as Mikrogen, Rosagrobioprom ROA and Bioprocess LLC as well as pressure groups such as the Russian Society of Biotechnologists and the Union of Biotechnology Industry. Since 2006 a number of regions have actively begun to develop and implement their own programmes of development within the sphere of biotechnology (the Republic of Tatarstan, Chuvashia, the Kirov Region, and others), and this trend is showing positive results. Another possible positive development is that the United Russia party has taken an interest in developing Russian biotechnology. One important aspect is the Strategy for the Pharmaceutical Industry Development to 2020, where the biopharmaceuticals industry is given an important role. There have also been targeted initiatives by the Ministry of Agriculture focusing on developing bioenergy.

The draft of the Development Strategy for the Biotechnology Industry in Russia 2010–2020, which was published in 2009, 401 was the second document prepared by the Russian biotech community. It hopes that the document will finally attract the attention of the Russian Government so as to start the revival of the Russian bioindustry. The government was to consider adopting it early in 2010. Earlier, the National Programme for 2006–2015 was almost completely ignored at the federal level, although it contributed significantly to the development of the biotechnology industry in the regions. In other words, the government's priorities

Aussian Federation (2009) 'The Government of Russia Will Present Development Strategy of the Biotechnology Industry in Russia 2010–2020', 10 December 2009, on the Internet: http://www.biorosinfo.ru (retrieved 16 December 2009).

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for the biotechnology area will probably be decided during President Medvedev's first term.

Establishing a national pharmaceuticals industry has been put on the national security agenda in Russia. Then President Putin stated in 2008 that the state must support the domestic pharmaceuticals industry in order to enable it to compete internationally. He claimed that foreign companies were using mafia-like methods when competing with Russian companies. 402 However, Russian companies will be unable to finance the multibillion dollar research programmes that are required to develop new pharmaceutical products. This is done mainly by large international pharmaceuticals companies. This explains the significant shares held by foreign companies in Russia. Most Russian citizens prefer to buy foreign brands of pharmaceutical products as they believe them to be more effective and safer, provided they can afford them. Alternatively they can purchase local generic alternatives of new drugs or products produced by companies of the former Soviet bloc. Russia has one of the fastest-growing pharmaceuticals markets in the world, but for foreign companies it is frustrating and fairly risky to enter the market. It would be going too far to describe the Russian pharmaceuticals industry as immune to the current economic instability: in particular the lack of access to capital for expansion and a weakening currency are substantial worries; but evidence suggests that the damage to date from the economic crisis has been limited. 403 It was estimated that the Russian market for pharmaceuticals would decrease by 9.1 per cent in 2009 due to the economic crisis. 404

At the highest political level it is clear, which are the challenges to achieve a functional innovation system, to promote innovative research in biotechnology and to create a competitive bio industry and domestic pharmaceuticals industry. In statements in November 2009, President Medvedev discussed the problems of innovation and the need for a competitive pharmaceuticals industry. He outlined the problems and how they will be resolved (see Appendix 2). The proposed

⁴⁰² Pravda (2004) 'Mafia Dominates Russian Pharmaceutical Industry', *Pravda online*, 29 November, 2004, on the Internet: http://www.garant.ru/iconf/report/83.htm (retrieved 26 February 2008); and Advis.ru (2007) 'Putin: Russia has to produce its own medicines', 6 March, on the Internet: http://www.advis.ru/cgi-bin/printnew.pl?786B7EAD-D01B-8142-9C66-8FB48231F376 (retrieved 7 March 2007).

⁴⁰³ Russian Pharmaceuticals & Health Care Report 2009, on the Internet:

http://www.businessmonitor.com/russia_pharma.html (retrieved 19 February 2009).

*Russia Pharmaceuticals and Health Care Report Q4 2009, Companiesandmarkets.com, 8

October 2009, on the Internet: http://www.companiesandmarkets.com/Summary-Market-Report/russia-pharmaceuticals-and-healthcare-report-q4-2009-161766.asp (retrieved 27 October

⁴⁰⁵ Presidential Address to the Federal Assembly of the Russian Federation, The Kremlin, Moscow, 12 November 2009, on the Internet:

http://eng.kremlin.ru/speeches/2009/09/10/1534 type104017_221527.shtml (retrieved 19 November 2009); and President Medvedev's article, 'Go Russia!', 10 September 2009, on the

modernization of Russia is planned to be carried out in 10–15 years, which is probably optimistic. It is easy to agree with the president's concern over the situation, but the question is how much of this is rhetoric and whether it will be possible in the near future to implement these ambitious plans. It is also questionable whether Russia can provide a competitive R&D environment in order to keep and recruit talented young scientists in biotechnology. The development of new drugs is a very expensive business that only large multinational companies with large resources can manage. This means that Russian companies must seek foreign investment and cooperate with foreign companies.

The goals set up in the Development Strategy for the Biotechnology Industry (Table 7) are very ambitious and the question is whether they can be reached if extraordinary measures are not taken. The historical record when it comes to the implementation of earlier ambitious programmes is far from encouraging. It is difficult to combine the two priorities of, first, establishing a competitive domestic industry in biotechnology and pharmaceuticals and, second, attracting foreign investment and establishing foreign partnerships. In a similar way, Russian scientists abroad and foreign scientists are to be encouraged to come back to Russia, but at the same time scientists in Russia who receive foreign research grants or who cooperate with research groups abroad are at times accused of working for foreign intelligence agencies. According to Anatolii Lokot, a member of the State Duma, scientists seeking Western funding and working closely with Western counterparts are viewed with some suspicion by the FSB. 406 Under President Boris Yeltsin foreign funding was tolerated as there was only very limited state funding available, but under President Putin the situation changed towards a higher risk for scientists receiving foreign support.⁴⁰⁷ International cooperation in the area of biotechnology will be absolutely necessary in order to develop Russian biotechnology and establish a competitive biotechnology industry. If Russia wants to catch up with Western countries in this very competitive area it will be tempting to continue or even intensify industrial espionage to catch up. And, even if this does happen, developments in biotechnology are so rapid that it is not enough to collect some detailed information to be able to produce and market a product. Russia stands before considerable challenges if it is to reach its ambitious goals in the biotechnology field. These challenges are intimately linked to the very broad policy choices that the political leadership will need to make if it is to succeed in its ambition to modernize Russia.

407 Ibid.

Internet: http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009).

⁴⁰⁶ Rich, Vera (2007) 'Scientists Risk Prosecution', *Times Higher Education*, 2 February 2007.

Appendix 1

The List of Russian Critical Technologies

(Those linked to biotechnology are highlighted.)⁴⁰⁸

- 1. Basic and critical military, special and industrial technology
- 2. Bioinformatics technology
- 3. Biocatalytic, biosynthetic and biosensor technology
- Biomedical and veterinary technology livelihoods and protection of human
- 5. Genomic and postgenomic technology of medicines
- 6. Cellular technologies
- 7. Nanotechnology and nanomaterials
- 8. Nuclear technologies, nuclear fuel cycle, safety of radioactive waste and spent nuclear fuel
- 9. Bioengineering technology
- 10. Hydrogen energy technologies
- 11. Technology mechatronics and the creation of microsystems technology
- 12. Technologies for monitoring and forecasting of the atmosphere and hydrosphere
- 13. New technologies and renewable energy
- 14. Technology protection, the livelihoods of the population and dangers of possession and use by terrorists.
- 15. Processing technologies, storage, transfer and protection of information
- 16. Technology resources assessment and forecasting of the lithosphere and the biosphere
- 17. Technologies of processing and utilization of man-made structures and waste
- 18. Technology and production software
- 19. Technology and production of fuels and energy from organic raw
- 20. Distributed computing technology and systems
- 21. Technology risk reduction and mitigation of natural and technological disasters
- 22. Technology creating biocompatible materials
- 23. Technology development of intelligent systems, navigation and control
- 24. Technology creation and processing of composite and ceramic materials
- 25. Technology creation and processing of crystalline materials
- 26. Technology creation and processing of polymers and elastomers

Aussian Federation (2008) List of Critical Technologies Approved by Order of the Russian Federation Government, No. 1243, 25 August; and Parliamentary hearings (2009) Working Papers for Development of the Strategy for the Biotechnology Industry.

- 27. Technology creation and management of new types of transport systems
- 28. Technology creation of membranes and catalytic systems
- 29. Technologies to create new generations of space-rocket, aviation and marine equipment
- 30. Technology for making electronic component base
- 31. Technology creating energy efficient transportation, distribution and consumption of heat and electricity
- 32. Technologies of creation of energy-efficient engines and propulsion systems for vehicles
- 33. Technology of environmentally sound resource-saving production and processing of agricultural raw materials and foodstuffs
- 34. Environmentally sound mining and mining

Appendix 2

President Medvedev addresses the Federal Assembly of the Russian Federation in 2009 on the problems of innovation and the need for a competitive pharmaceutical industry⁴⁰⁹

'Instead of a primitive raw materials economy we will create a smart economy producing unique knowledge, new goods and technology of use to people'... 'We must begin the modernisation and technological upgrading of our entire industrial sector. I see this as a question of our country's survival in the modern world'... 'These are the key tasks for placing Russia on a new technological level and making it a global leader. These priorities include introducing the latest medical, energy and information technology, developing space and telecommunications systems, and radically increasing energy efficiency. A special presidential commission has approved specific projects in all of these five areas and has drawn up detailed timetables for their implementation'. 'One of the most promising areas is to make use of the widespread bio-resources we have, above all timber, peat, and industrial waste, as energy sources (biofuels)'. He went on to say: 'The modernisation area of top importance for our people is developing medical technology, medical equipment, and the pharmaceuticals industry. We will provide people with quality and affordable medicines and also the latest technology for preventing and treating diseases, especially the diseases that are the biggest causes of sickness and death in our country.

We have already drawn up a list of strategically important medicines that should be produced here in Russia. This includes the most expensive medicines, in particular medicines for treating cardiovascular diseases and cancer. We will need to produce more than 50 such medicines so that everyone who needs them will be able to receive timely treatment. Also we will soon dramatically increase production of our own medicines for treating the most common diseases such as colds and flu. I think that Russian companies have the ability to produce medicines and technology that would find demand on the global market. For this we need to work more actively on developing partnerships with leading foreign developers and producers, who can contribute to organising advanced medical research in Russia itself. We will also use the public procurement mechanism to encourage domestic production of medicines and technology. Within five years, Russian-made medicines should account for at least a quarter of the medicines

http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009).

⁴⁰⁹ President of Russian Federation (2009) 'Presidential Address to the Federal Assembly of the Russian Federation', The Kremlin, Moscow, 12 November, on the Internet:

market here and for more than half of the market by 2020'.... 'This requires us to establish effective mechanisms for supporting them, and also for attracting to Russia Russian and foreign scientists of repute, and entrepreneurs with experience in commercialising new developments. This is a complex business. We should simplify the rules for recognising degrees and diplomas awarded by the world's leading universities, and also the rules for hiring the foreign specialists we need'....'I am instructing the Government to expand the system of the basis of tenders for those developing technology'....'University-based business incubators would give graduates the chance to learn how to turn their scientific ideas into profitable business projects. I think this kind of idea deserves our full support. I stress that not only the state but also our major companies should play their part by placing advance orders for the results of the research carried out. You could say this is all part of their social responsibility. A large share of projects should go through an international expert evaluation and be carried out in partnership with foreign centres and companies'. Further, in an article entitled 'Go Russia': 410 'Russia will take a leading position in the production of certain types of medical equipment, sophisticated diagnostic tools, medicines for the treatment of viral, cardiovascular, and neurological diseases and cancer. We will encourage and promote scientific and technological creativity. First and foremost, we will support young scientists and inventors'.... 'Public and private companies will receive full support in all endeavours that create a demand for innovative products. Foreign companies and research organisations will be offered the most favourable conditions for establishing research and design centres in Russia. We will hire the best scientists and engineers from around the world'. This shows the priorities as laid out by the highest leadership as well as insight into the problems that have been well known for observers for a long time. It is easy to agree with the president's concern over the situation but the question is how much of this is rhetoric and whether it will be possible in the near future to implement these ambitious plans. How is this going to be financed? As Medvedev pointed out: 'But this year (2009), we are expecting to see the GDP decline by about 7.5%. This figure is very serious, and I want to emphasise again that our forecasts had been far less severe'.411

'Modernisation, we are keen to make sure that it takes place as quickly as possible. Not a year, not two, not three, but maybe 10–15 years – that is a

410 Medvedev (2009) 'Go Russia!'.

⁴¹¹ Kleimenov, Kirill (2009) 'Conversation with Dmitry Medvedev, Answers to questions from Director of News Programmes at Russia's Channel One Kirill Kleimenov', 11 October 2009, on the Internet: http://eng.kremlin.ru/speeches/2009/09/10/1534_type104017_221527.shtml (retrieved 19 November 2009).

412 Ibid.

perfectly plausible time frame in which to create a new economy, an economy that will be competitive with other major world economies ,412

Appendix 3

Some major Organizations, Clusters and research Institutes Active in the Area of Biotechnology

Russian Society of Biotechnologists and Union of Enterprises of the Biotechnology Industry

Vice-President: Vasily Raif Gayanovich Juravleva st. 6, 107023, Moscow,

Postaladdress: 119296, Moscow University Ave 9

Tel.: (495) 545-37-84, 8-916-640-76-18

Fax: (495) 545-37-84

E-mail:sb@biorosinfo.ru,obr@biorosinfo.ru

Website: http://www.biorosinfo.ru Website: http://http://www.sbiotech.ru

The Russian Society of Biotechnologists was set up in 2003 and has over 3700 members. It cooperates with the government and non-governmental organizations in Russia and internationally. The Union of Enterprises in the BioIndustry Industry has over 50 companies. The society is a member of the European Federation of Biotechnology. Main objectives are:

- to develop a knowledge-based bio economy in the Russian Federation
- promoting biotechnology as a priority in science and technology;
- promoting scientific and technological capabilities in biotechnology;
- ensuring the exchange of scientific ideas and technical expertise;
- promoting collaboration between scientists internationally; and
- creating conditions for creative work and innovation.

BIOPREPARAT Russian Joint Stock Company (RJSC)

General Director Prof. Ramil Usmanovich Khabriev 4a Samokatnava St. 109033 Moscow

Tel.: +7 (095) 3622282, +7 (095) 3622287 Fax: +7 (095) 3621526, +7 (095) 3622818 Director General: Mr. Vladimir Koleshnikov

The Biopreparat RJSC was set up in 1994 through reorganization of the state concern Biopreparat into an open joint stock company. Around 36 000 persons are engaged in production. Biopreparat designs new generations of therapeutics

and preventive agents against infectious diseases. Biopreparat is a co-owner of 20 industrial enterprises that manufacture more than 1000 items. Examples of these enterprises are the Sintez Joint Stock Commercial Company (Kurgan), Biosintez Open Joint Stock Company (Penza), Biokhimik Open Joint Stock Company (Saransk), Krasfarma Open Joint Stock Company (Krasnoyarsk) and Moskhimfarmprepararaty FGUP (Moscow). There are four state research centres with about 6000 scientists in microbiology, biotechnology, genetic engineering, immunology and biophysics, six research institutes, two pilot design bureaus and two design institutes involved. Biopreparat's enterprises and organizations are located in Moscow, the Moscow Region, St Petersburg, Kurgan, Penza, Novosibirsk, Krasnoyarsk, Saransk, Novokurnetsk, Omutnisk, Berdsk, Loshkar-Ola, Kirishi, Kirov, Yefremov, Tver Region, Vladimir Region and Tuimazy.

The state shares amount to 5.1 per cent of its capital. Annually products are produced for 1000 descriptions, an output to a value of around 10 billion roubles per year, accounting for almost 35 per cent of the entire Russian output of medical products (of this 8 billion roubles is for drugs and 1.7 billion roubles for medical engineering articles). A total of 36 000 people are involved in production. The total output of products is made up of 2.8 per cent agricultural drugs, 2.8 per cent machine building, 16.2 per cent medical equipment and 78.2 per cent drugs. Examples of products are antibiotics, blood substitutes, infusion solutions, amino acids, blood coagulation-affecting drugs, anti-inflammatory agents, anti-depressants, treatment for malignant neoplasma, vitamins, antiviral drugs, immunomodulating agents, antimycotic agents, bacterial and viral diagnostics, medical equipment, pharmaceuticals utensils, enzymatic preparations, plant protective agents, feed products and process control devices. Biopreparat was described in a previous FOI report. 414

Major research areas:

- basic research in virology, bacteriology, biotechnology, immunology and research on instrument-making and medical engineering;
- new generation of therapeutics against infectious diseases;
- recombinant compounds, such as interferons, interleukins, erythropoietin;
- diagnostic test systems and differential culture media;
- methods and technical means for controlling technical processes and biological air pollution; and
- research equipment for medical and industrial biotechnology.

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⁴¹³ Information based on booklet from BIOPREPARAT.

Appendix 4, pp. 127-34.
Appendix 4, pp. 127-34.

BIOMAC NP Consortium

Tel.: 095 234 3200,

E-mail biomac@apico.msk.ry

The non-commercial partnership Biomac Consortium was created in 2001 and incorporates 60 Russian and foreign participants. Biomac was formed on the initiative of several ministries to promote the transformation of research into innovations to industrial products in biotechnology. Members of the consortium are scientific and educational institutions (21 entities), production and engineering organizations (15), banks and other organisations in the financial sector (3), marketing, consulting and societal organizations (7). The consortium provides a bridge between research and industry and also a channel to seek venture capital, cooperation within Russia as well as internationally, and the formation of incubators, techno-parks, etc. The consortium also develops recommendations for development strategies in the biotech sector. 415

Goals and main directions:

- Promoting domestic and foreign investments in biotechnological projects and international partnerships;
- Analytical and consulting activities;
- Establishing international contacts and cooperation;
- Biotechnology transfer; and
- Participation in the development of regulatory legal acts, standards and technical regulations.

Biomac coordinates of the international cooperation in biotechnology for:

- plant growing and plant protection;
- increasing the efficiency of agriculture;
- livestock breeding, animal industry, and veterinary medicine;
- preservation of the environment and recycling of waste;
- public health care, including diagnostics and analysis kits;
- improving industrial processes and obtaining new products; and
- improving food quality and innovating in the food industry.

There is especially active cooperation with Belarus, Kazakhstan and Ukraine. The companies involved are RAO Biopreparat, RAO Risagrobioprom, and OOO FarmaDon.

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⁴¹⁵ Biomak homepage, on the Internet: http://www.biomac.ru/ (retrieved 7 May 2007).



MICROGEN, the Federal State Unitary Enterprise Research-Production Unit on Medico-immunobiological Preparations

Russian Ministry of Health and Social Development Address: Zubovsky Blv., 4, Moscow, Russia, 119021

Tel: (095) 981- 6200, Fax: (095) 981-6209

Website: http://www.microgen.ru/

Microgen is a government company and scientific production union established in 2003 with 14 microbiological facilities, nearly 8000 employees and a substantial production capacity (more than 400 items). The aim is to produce vaccines for the Russian population and one is the flu vaccine Grppel. Mikrogen was the largest pharmaceuticals producer (by turnover) in Russia in 2006. 417

TEMPO (Technology, Epidemiology, Marketing, Production and Education) Center for New Medical Technologies

Deputy Director: Dr. Yuri Remnev, Tel.: 7 (495) 708-39-51, 708-39-51

E-mail: <u>info@nptemp.ru</u>

Website: http://www.nptemp.ru

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⁴¹⁶ Mikrogen homepage, on the Internet: http://www.microgen.ru/ (retrieved 7 May 2007); and Bairamashvili and Rabinovich (2007) 'Russia through the Prism', p. 804.

⁴¹⁷ Bespalov, N. (2006) 'Sliianiia i pogloshcheniia v proizvodstvennom sektore rossiiskogo farmatsevticheskogo rynka' [Mergers and Acquisitions in the Industrial Sector of the Russian Pharmaceuticals Market], *Farmatsevticheskii vestnik*, No. 26, on the Internet: http://www.pharmvestnik.ru/cgi-bin/statya.pl?sid=11182 (retrieved 8 May 2007).

The Biotechnology Consortium TEMPO is a non-commercial partnership that has as it members Russian R&D, manufacturing & sales organizations. It was formed in 2002 to promote conversion and threat reduction in the biological field, by bridging the gap between research and industry. The International Science and Technology Centre (ISTC) is a founding member of the organization, with another 17 member organizations and about 5500 staff, including many highly qualified personnel. Its main aims are to identify commercial niches with potential for development, identify research results and innovations with the highest potential for commercialization, analyse relevant Russian and foreign legislation, and search for investors. Examples of activities are courses in GMP and GLP.

TEMPO focuses on providing support in regulatory affairs, industry outreach, and innovation.

Its members' areas of specialization include R&D, the manufacture of diagnostics and biopharmaceuticals against human diseases, veterinary products, space biotechnology, and biological instrumentation, including:

- Coordination of R&D;
- Educational training programmes for member specialists;
- Quality improvement of preclinical drug studies;
- Development of biotech products and pilot production;
- Clinical trials;
- Biosafety and biosecurity issues;
- Education on standards, GLP, GMP, GCP (GXP) and for regulatory affairs; and
- Providing support for research, licensing, marketing, preclinical studies and coordination.

Members

- Biocad Center of Immunological Engineering Ltd., http://www.biocad.ru
- Open Joint Stock Company Biochimmash, Institute of Applied Biochemistry and Machine
- Building, http://www.bioplaneta.ru
- Federal State Research Center of Virology and Biotechnology (Vector), http://www.vector.nsc.ru
- Gamaleya Scientific Research Institute of Epidemiology and Microbiology, http://www.gamaleya.ru

419 NP 'Tempo' homepage, on the Internet: http://www.nptemp.ru (retrieved 7 May 2007).

⁴¹⁸ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/profiles-of-russian-partner-institutions/center-for-new-medical-technologies-tempo (retrieved 10 February 2009).

- Joint Stock Company Institute of Immunological Engineering (IIE)
- Institute of Physiologically Active Compounds of the Russian Academy of Sciences (IPAC), http://www.ipac.ac.ru
- Open Joint Stock Company Russian Research Center for Molecular Diagnostics and Therapy (RCMDT), http://www.rrcmdt.narod.ru
- State Scientific Research Center for Applied Microbiology (SRCAM), http://www.obolensk.org
- St Petersburg Pavlov State Medical University (SPPSMU)
- State Research Center for Toxicology & Hygienic Regulation of Biopreparations (RCT&HRB), http://www.toxicbio.org
- State Scientific Research Institute of Biological Instrument Making (SRIBIM)
- State Research Institute of Highly Pure Biopreparations (SRIHPB), http://www.hpb-spb.com
- M. M. Shemyakin and Yu. A. Ovchinnikov Institute of Bioorganic Chemistry/ Pushchino Branch, http://www.ibch.ru
- Federal State Scientific Institute of Toxicology, http://www.toxicology.sp.ru
- Research Unit on Medico-immunological Preparations NPO Microgen www.microgen.ru
- I. M. Sechenov Moscow Medical Academy (MMA), http://www.mmascience.ru
- D. I. Ivanosky Institute of Virology RAMS, http://www.virology.ru
- The National Center of Biotechnology of the republic of Kazakhstan, http://biocenter.ru/

BIOPROCESS GROUP LLC

8-1, Nauchnii subw.

Moscow, 117246, Russia Tel.: +7 495 411-85-94 Fax: +7 495 120 93 07 E-mail: info@bioprocess.ru Website: http://www.bioprocess.ru

Bioprocess develops efficient technologies for the production of recombinant proteins. In 2002 it launched its Pilot Production Facility in Moscow. The company uses a wide range of genetic engineering and biotechnology methods, such as gene cloning, engineering of producing strains, laboratory and large-scale fermentation and protein purification, protein analysis, etc. The technology for producing recombinant human interferon alfa-2b has been developed. Bioprocess will shortly start produce the API of recombinant human erythropoietin (EPO) under a licence agreement and filgrastim (GCSF). It intends to build a large-scale production facility capable of satisfying domestic demand and competing in

other markets. Bioprocess has acquired a majority interest in Biomed-Mechnikov Joint Stock Company, a biopharmaceuticals manufacturer based in Petrovo-Dalnee near Moscow. Control over Biomed offers Bioprocess a number of strategic advantages.



Binnofarm ZAO

Kaluzhskaia, Nauchnyi pr., d. 6, ph. 117246, Moscow, Russia, Tel: +7(495) 510-3288

In 2009, Binnofarm opened a pharmaceuticals factory in Zelenograd. The new company will become one of the largest Russian producers of medicines, operating in accordance with GMP. The main biotech product is a vaccine against viral hepatitis B. Binnofarm aims to become a leader in the field of biotechnology for pharmaceuticals and in the next three years to become one of the three leaders of the domestic pharmaceuticals industry. It has its own development of innovative biotech drugs, including those intended to treat previously incurable diseases (cancer, HIV, multiple sclerosis), as well as diagnostic biochips. Binnofarm plans to create a scientific and production complex in Zelenograd for proteomics, in collaboration with the world's leading pharmaceuticals companies. This will include developing monoclonal antibodies for the treatment of previously incurable diseases; cell technologies to develop new therapies for the treatment of cancer and infectious diseases genetherapeutic vaccine and recombinant protein preparations; and development of antiviral vaccines.

Binnofarm produces a range of finished innovative and generic medicines. The company began the first industrial production of a vaccine for hepatitis B in 2005. It is the only company in Russia conducting full-cycle vaccine production from substance to final-form product and is developing production of an array of immunobiological medicines. Binnofarm also produces central nervous system analgesics together with the Federal State Enterprise GZMP, which accounted for around 50 per cent of the Russian market in 2006.



BIOCAD, Center of Immunological Engineering Ltd

Dmitry Morozov, Chairman of the Board of Directors, Evgeny Topchiev, CJSC Biocad CEO

The Center of Immunological Engineering Ltd., Biocad Address Moscow Region, Krasnogorsk m., pos. Petrovo future

Tel: 7 (495) 992-6628, Fax: 7 (495) 992-8298

E-mail: biocad@biocad.ru, E-mail: mogutnova@biocad.ru

Website: http://www.biocad.ru.

BIOCAD⁴²⁰ is privately owned company that started as a distributor of generic versions of popular medications. It develops and manufactures both generic and innovative biotechnology products in the Moscow Region. It has a research facility the Center of Immunological Engineering (CIE), (located in Lyubuchany), which develops novel therapeutics based on cytokines, antibodies and other recombinant proteins. In 2007 its share of the Russian market for immunobiological products was 5 per cent. BIOCAD is developing a new facility capable of large-scale production of recombinant proteins in mammalian cell cultures.



The Joint Stock Company Institute of Immunological Engineering (IIE)

Address: Luybuchany, Moscow Region, Chekhov District, 142380

Contact: Dr. Sergey Pchelintsev, General Director

Tel: (095) 996-1037 Fax: (095) 996-1039

E-mail: <u>imeng@tdn.ru</u>

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⁴²⁰ Information based on the U.S. State Department BII website, on the Internet:

http://biistate.net/wp/wp-content/uploads/2008/10/biocad.pdf (retrieved 20 February 2009).

⁴²¹ Nature Biotechnology (2005) Vol. 23; and Wall Street Journal, 15 April 2002).

This is a subsidiary of BIOCAD established in 2001 on the basis of the former Soviet Institute of Immunological Engineering (founded in 1978). There is production of artificially produced human interferon alpha-2 (Genferon) and Leykostin to treat cancer. Twenty other drugs are in different stages of development. The IIE carries out fundamental and applied research in the fields of immunology, microbiology and medicine, to develop preventative measures and treatments for infectious diseases, as well as for the mitigation of acts of bioterrorism and biological accidents. There are facilities to work with infectious material of biosafety levels 3–4.

Research areas covered:

- Immunology of vaccine and infectious processes in the pathogenesis of infectious diseases:
- Recombinant preparations for use as immune modulators, prophylactics and therapeutics;
- Preclinical trials of medical prophylactic preparations; and
- Development of enteric forms of vaccines and cytokines.

Pushchino Research Center (PRC)

Chairman: Anatoly Ivanovich Miroshnikov Dr. Sci. (Chem.), Member of the

RAS

Pushchino Research Center, Russian Academy of Sciences, PNTS RAS

Tel.: (495) 6327868, (4967) 732636

Fax: (4967) 732636

Address: 142290, g.Puschino, Moscow Region.,

PAH Prospect Nauki, 3, PNTS RAS

E-mail: <u>nazarova@psn.ru</u> Website: <u>http://www.psn.ru</u>

PRC includes the following institutes:⁴²³

- Pushchino branch of the Shemyakin and Ovchinnikov Institute of Bioorganic Chemistry
- Institute of Protein Research
- Institute of Cell Biophysics
- Institute of Biochemistry and Physiology of Microorganisms

⁴²² Information based on the U.S. State Department BII website, on the Internet:

http://biistate.net/wp/wp-content/uploads/2008/10/iie.pdf (retrieved 20 February 2009).

Presentation, Pushchino Research Centre, on the Internet:
http://www.owwz.de/fileadmin/Biotechnologie/BioVeranst/Pushchino 2008/Miroshkinov.pdf (retrieved 16 February 2009).

- Institute of Mathematical Problems in Biology Institute of Basic Biological Problems
- Institute of Physicochemical and Biological Problems of Soil Science
- Institute of Theoretical and Experimental Biophysics
- Branch of Institute of Bioorganic Chemistry
- Institute for Biological Instrumentation Pushchino Radio Astronomy Observatory of Astro Space
- Center of Lebedev Physical Institute.

Pushchino International Technopark 424

Address Shabolovska 12, Moscow

Tel.: +7(095) 785 4221, Fax.?? +7(095) 236 5417,

E-mail: <u>biopark@rambler.ru</u>

The non-commercial partnership International Technopark Pushchino (ITP) was established in 2005, including a branch in Serpukhov town (Moscow Region). Biomac is one of the co-founders⁴²⁵ and the Pushchino Science Center of the Russian Academy of Sciences is one of the participants. The aim of the technopark is to promote biotechnology and to initiate business ventures. It is located in the science town where the Pushchino Scientific Centre lies.

Yuri Kalinin is the chairman of the board of the Pushchino International Technopark. His company, 21st Century Biotechnology OJSC, is a member of Biomac. He was a leading figure in the Soviet biological weapons programme in his role as head of Biopreparat (now one of the founders of Biomac), and thus he also has ties to many other organizations in Biomac and NP Tempo. Kalinin is also the chairman of the Russian medical producers' association RosMedProm. He has held other influential posts in the past, for example as a member of the Biopreparat board after stepping down as a director. 427

425 Elevar Holding homepage, on the Internet: http://www.npoelevar.ru/1/2/6_1.htm (retrieved 7 May 2007).

Pushchino Scientific Centre homepage, on the Internet: http://www.psn.ru/ (retrieved 7 May 2007)

⁴²⁶ Kalinin's biography at Mezhdunarodnyi ob'edinennyi biograficheskii tsentr (2002), on the Internet: http://www.biograph.comstar.ru/bank/kalinin_vuri.htm (retrieved 13 May 2007); and Mednovosti (2007) 'Podpisano soglashenie o sotrudnichestve Federal'nogo fonda OMS, ARFP i Assotsiatsii Rosmedprom' [Cooperation Agreement between the Federal OMS Fund, ARFP and Rosmedprom Association is signed], on the Internet:

 http://www.medportal.ru/mednovosti/corp/2007/03/14/foms/ (retrieved 12 May 2007).
 Roffey, Unge, Clevström and Westerdahl (2003), Support to Threat Reduction, pp. 91-98.

JSC Bioran

JCS Bioran was founded in June 2006 as a biotech company for the design and construction of a new multipurpose biotechnological facility supported by the Moscow regional government and the Russian Academy of Sciences. In 2011 Bioran's new facility in Pushchino, Moscow Region, will be completed and start up. The facility will initially produce human insulin but production technologies for other biotechnological products will also be developed. The process technology for human insulin was developed by the Institute of Bioorganic Chemistry M. M. Shemyakhin and Y. A. Ovchinnikhov, together with the Russian Academy of Sciences, and transferred to JSC Bioran under a licence agreement. The new plant in Pushchino is designed to become the most state-of-the-art biotechnological production facility in Russia, capable of manufacturing several biotechnological products. It is hoped that this project will reduce the Russian dependence on imports of biopharmaceutical products.



Institute of Protein Research RAS

142290, Pushchino, Moscow Region, Russia

Tel.: (495) 9240493, (4967) 730542

Fax: (495) 9240493

Director: Lev P. Ovchinnikov, Dr. Sci. (Biol.), Prof. Member of RAS

Research areas covered:

Studies of molecular mechanisms of protein biosynthesis including the following:

- structural basis of functioning of ribosomes and their components;
- regulation of protein biosynthesis;
- development of a large-scale cell-free system of protein biosynthesis;
- development of cell-free systems of RNA replication;
- structural studies of proteins and their biological functions including: processes of formation of the 3-D structure of proteins; development of the theory of the 3-D structure of proteins; protein functioning; primary and 3-D structures of proteins by classic methods (X-ray analysis, microcalorimetry, optical techniques, etc.);
- gene and protein engineering; and

- chemical synthesis of biologically active polypeptides and protein fragments.

Institute of Cell Biophysics RAS

Director: Evgeny E. Fesenko, Dr. Sci. (Biol.), Prof. Corr. M. of RAS

142290, Pushchino, Moscow Region, Russia

Tel.: (495) 9255984, (4967) 730519

Fax: (4967) 330509

E-mail: <u>admin@ibfk.nifhi.ac.ru</u> Website: http://www.icb.psn.ru

Research areas covered:

Mechanisms of reception and intracellular signalling;

- Receptors, mediators, ion channels;
- Principles of molecular recognition;
- Cell structure and functions;
- Cell-membranes:
- Macromolecules and macromolecular complexes;
- Cell-cell interactions;
- Cryoconservation of cells and cell engineering;
- Effects of physical factors on the cell and cell systems; and
- Mechanisms of cellular stress and hibernation.

Institute of Basic Biological Problems IFPB RAS

142290, Pushchino, Moscow Region, Russia

Tel.: (4967) 733601 Fax: (4967) 330532

Director: Vladimir A. Shuvalov, Dr. Sci. (Biol.), M. RAS

E-mail: <u>ifpb@issp.serpukhov.su</u>

Research areas covered:

 Molecular mechanisms underlying the biological processes of energy transformation, energy conversion and storage in photosynthesis; structure and functions of membranes and supramolecular complexes involved in the biological transformation of energy and metabolites, photo-biotechnology;

- Physico-chemical problems of ecosystems stability, environmental biogeochemistry and monitoring of its components, ecophysiological and biochemical problems of ecosystems adaptation under anthropogenic impact; and
- Molecular mechanisms of genetic information expression; formation of functionally active proteins; regulation of biochemical processes; effects of physical factors on biological systems; bioreceptors.

Skryabin Institute of Biochemistry and Physiology of Microorganisms RAS

Director: Alexander M. Boronin, Dr. Sci. (Biol.), Prof. Corr. M. RAS

142290, Pushchino, Moscow Region, Russia

Tel: (495) 956-33-70 Fax: (4967) 73-07-62

E-mail: <u>boronin@ibpm.serpukhov.su</u> Website: http://www.ibpm.ru/

Research areas covered:

- Microbial diversity and its resources;

- Physiochemical interactions of microorganisms with the environment;
- Molecular mechanisms underlying the functioning of genetic systems of microorganisms; and
- Use of microorganisms in biotechnology.

Institute of Physicochemical and Biological Problems of Soil Science RAS

Director: Valery N. Kudeyarov, Dr. Sci. (Biol.) 142290, Pushchino, Moscow Region, Russia

Tel.: (4967) 731896 Fax: (4967) 330595

E-mail: soil@ISSP.serpukhov.su Website: http://www.issp.psn.ru

Research areas covered:

- Physicochemical and biogeochemical soil processes, the membrane and barrier role of soils in the biosphere;
- Role of terrestrial ecosystems in global and local biogeochemical cycles of elements;

- Spatial organization, functioning mechanisms, evolution of soils and prediction of the state of ecosystems of different levels;
- Mechanisms and modelling of the resistance of ecosystems to the action of natural and anthropogenic stress factors;
- Genesis, physicochemistry and microbiology of the cryopedosphere; and
- Ecological monitoring, bioremediation and rehabilitation of polluted and degraded soils and landscapes.



Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry, Russian Academy of Sciences, Moscow and Pushchino

Address: Miklukho-Maklaya Str., 16/10, Moscow, Russia, 117997

Tel.: (095)-335-0100 Fax: (095)-335-0812 E-mail: root@mail.ibch.ru Website: http://www.ibch.ru/ For Pushchino Branch:

142290, Pushchino, Moscow Region, Russia

Phone: (495)9252342, (4967)731719, Fax: (4967) 330527

E-mail: fibkh@fibkh.serpukhov.su, murashev@fibkh.serpukhov.su

Website: http://www.fibkh.serpukhov.su/

Director: Vadim T. Ivanov, Dr. Sci. (Biol.), Prof. M. RAS.

The Shemyakin Ovchinnikov Institute of Bioorganic Chemistry (SOIBC), originally known as the Institute for Chemistry of Natural Products (ICNP), was set up in 1959. The ICNP was later renamed after two well-known Soviet scientists, Professors Michael Shemyakin and Yuri Ovchinnikov. The SOICB's major research activities include such disciplines as molecular immunology, signal transduction, basic and applied biotechnology and molecular ecology, to name only a few. The Institute also provides high-level education and training in physicochemical biology and biotechnology, as well as information services. In addition, SOICB also participates in international collaboration such as the establishment of the International Center for Biotechnology Research, bringing in foreign investments. As a premier centre for the study of physicochemical

biology, its basic studies in peptides, proteins, nucleic acids and lipids have been important for the development of modern biotechnology into Russia.

Research areas covered:

- Bioorganic chemistry;
- Molecular biology;
- Biochemistry;
- Plant biology;
- Biotechnology;
- Protein and gene engineering;
- In vitro and in vivo protein biosynthesis;
- Transgenic plant construction;
- Plant clonal micropropagation;
- Laboratory animal strains;
- Preclinical development; and
- Biological activity and preliminary screening.

The Institute for Biological Instrumentation of the RAS (IBI RAS)

Director: Evgeny A. Permyakov, Dr. Sci. (Biol.), Prof.

142290, Pushchino, Moscow Region, Russia

Tel.: (495) 6245749, (4967) 730478

Fax: (4967) 330522 E-mail: ibp@ibp-ran.ru

Website: http://www.ibp-ran.ru

Established on the basis of the NPO Biopribor Corporation in 1994 (former Special Design Bureau for Biological Instrumentation of the USSR Academy of Sciences established in 1965). Since 1965 it has developed more than 200 types of instrument for both unique and routine studies in biological sciences.

Research areas covered:

- Instruments for thermodynamic studies;
- Spectral and optical instruments;
- Equipment for cultivation of microorganisms;
- Instruments and equipment for biochemistry;
- Instruments and equipment for cell studies;
- Instruments and equipment for energy and resource saving;
- Instruments and equipment for biomedicine;
- Development of methods of surface analysis; and
- Studies of physical, chemical and functional properties of metal-binding proteins.



The State Research Center of Virology and Biotechnology (VECTOR)

Federal Service for Surveillance in Consumer Rights Protection and Well-being Director General Prof. I. Lyia G. Drozdov, Dr.Sci.

Tel.: +7 (383) 336-6010 Fax: +7 (383) 336-7409

E-mail: <u>DROZDOV@VECTOR.NSC.RU</u> Website: http://WWW.VECTOR.NSC.RU,

VECTOR is one of the largest scientific research and production complexes in the Russian Federation and was established in 1974. It has become a leading research and production centre in the areas of virology, molecular biology, genetic engineering, biotechnology, epidemiology, ecology and developing novel technologies for the diagnosis, treatment and prevention of infectious diseases. VECTOR's basic and applied research programme has resulted in the development of novel vaccines, diagnostics, antiviral therapeutics and delivery systems. 428

Research areas covered:

- Pathogenic mechanism of filovirus infections;

- Collection of cloned DNA copies of genomic fragments of Marburg, Ebola, Lassa, variola, tick-borne encephalitis, Japanese encephalitis, haemorrhagic fever with renal syndrome, herpes type 6, chickenpox, human T-cell leukaemia, measles, rubella, hepatitis C, etc.;
- Complete genomes of Venezuelan equine encephalomyelitis, tick-borne encephalitis, Marburg and Ebola viruses, as well as strains of variola virus:
- Discovery of antiviral activities of several novel preparations;
- Candidate vaccines against human immunodeficiency virus type 1 (HIV-1);
- New biotechnological methods for creating next generation therapeutic, preventive, and diagnostic preparations, such as artificial

⁴²⁸ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/wp-content/uploads/2008/10/vector.pdf (retrieved 10 August 2009).

- immunoglobulins, recombinant bacterial and viral strains, which show promise as live vaccines;
- Development of analogues of recombinant cytokines (interferons and TNF) with improved biological properties, including resistance to proteolysis;
- Collections of HIV, hepatitis C, hepatitis A, cytomegalovirus, and HFRS strains;
- New methods for sampling biological aerosols and their characterization according to aerodynamic diameter and polarizability of biological particles in the magnetic field;
- New forms of vaccines and therapeutics (measles vaccine and human recombinant erythropoietin) for oral administration; and
- The antiviral Ridostin an interferon inducer displaying immunostimulating and antiviral activities –is being successfully introduced into clinical practice.

SRC VB VECTOR carries out research on the following agents.

- Variola (smallpox) virus
- Ebola and Marburg viruses
- Lassa and Machupo viruses
- Eastern equine encephalomyelitis virus
- Venezuelan equine encephalomyelitis virus
- Crimean-Congo hemorrhagic fever virus
- Tick-borne encephalitis virus and Japanese encephalitis virus
- Hemorrhagic fever virus with renal syndrome
- Influenza virus
- Other orthopoxviruses pathogenic for humans and animals
- SARS-associated coronavirus
- Viruses of hepatites A, B, C
- Cytomegalovirus and herpesviruses
- Measles and mumps viruses
- Rubella virus
- Human immunodeficiency viruses HIV-1 and HIV-2
- Animal and fish viruses
- M.tuberculosis
- Borrellia burgdorferi (Lyme disease)



The State Research Center for Applied Microbiology & Biotechnology SRCAM&B

Director: Dr. I. Dyatlov, SC.D. (MED), Prof.

Federal Service for Surveillance in Consumer Rights Protection and Well-being

Obolensk, Moscow Region

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The State Research Center for Applied Microbiology and Biotechnology is part of the Russian Federal Surveillance Service in the field of public health. The Center was founded on the basis of the State Research Center for Applied Microbiology in compliance with a decree of the Government of the Russian Federation. According to the decree, the mission of the Center is to carry out basic and applied research in epidemiology, bacteriology and biotechnology aimed at assuring the population's well-being, as well as to manufacture biotechnological products on pilot and large-scale levels. Research is carried out involving various bacterial pathogens, including those causing especially dangerous infections (anthrax, plague, tularaemia, glanders, melioidosis, and cholera). Recently, the facility for handling SPF laboratory animals (rabbits, hamsters, mice and rats) has been renovated and there is an installation for studies involving inhalation challenges of animals.

Research areas covered:

Technology of revertase production;

- Improved technologies of production of anthrax and typhoid fever vaccines;
- Technology for the production of human gene-engineered insulin;
- Bacterial formulations to control agricultural pests;

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⁴²⁹ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/wp-content/uploads/2008/10/srcam.pdf (retrieved 10 March 2010).

- Experimental mouse model of chronic/latent tuberculosis for testing new anti-tuberculosis drugs;
- NMR-relaxometer-analyser to control biotechnological processes;
- Theoretical work in the area of electro-orientation of particles, and as a result, new equipment for investigating cell populations on the basis of the electro-optic effect;
- Production of diagnostics and nutrient media;
- Non-pathogenic fungal and bacterial strains collected from Russian national parks, capable of producing biologically active substances; and
- Research and development has led to the successful production of a recombinant human insulin-producing microorganism, which resulted in the formation of the Joint Stock Company National Biotechnology, which is now commercially producing active pharmaceutical ingredients for the Russian market.

New research programme

- Diagnosis, prevention and cure of especially dangerous infections;
- New vaccines and therapeutics for prophylaxis and cure of especially dangerous infections will be developed and scaled up for production;
- Biomedical aspects of infectious disease, including microbiology of pathogens, molecular bases of pathogenicity and immunogenicity;
- New principles and methods of detection and identification of pathogenic bacteria. Procedures of diagnostics and prophylaxis of especially dangerous infections will also be developed;
- Biological safety and bioterrorism countermeasures;
- Improving the quality of diagnostic nutrient media; and
- Production of diagnostics and test systems for the needs of medicine.



Open Joint Stock Company Institute of Applied Biochemistry and Machine Building Biochimmash

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Director; Dr. Andrey Moshkin,

Tel.: 7 (495) 159-3170 Fax: 7 (495) 156-2897

E-mail: mag@bio.su

Website: http://www.bioplaneta.ru, info@bioplaneta.ru, info@biochimmash.ru

The Institute was founded in 1974 as the All Union Scientific Institute of Applied Biochemistry and became a Joint Stock Company in 1994. Bioplanet is used as a trade name. Biochimmash specializes in research, development and production in the following areas: phytomedicine and veterinary products, environmental protection and remediation, oil degradation, plant protection, disease-control biopesticides, and plant growth stimulators. In addition, Biochimmash is pioneering basic and applied space biotechnology, and specialized equipment for biological research including spray-drying. It has provided two critical functions to the innovation cycle: the scaling up of laboratory developments to industrial scale, and production based on these novel techniques. The staff includes around 200 highly qualified specialists (in 1979 there were 1500 personnel) with an extensive publication record and multiple patents.



Gamaleya Scientific Research Institute of Epidemiology and Microbiology

Director, Alexander L. Gintzburg, Prof. M. of RAMS, Phone (499) 193-3001).

Russian Academy of Medical Sciences

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Website: http://www.gamaleya.ru.

There are eight departments with 40 laboratory units and a staff of 750 scientists, and 230 employees are engaged in production. Gamaleya is Russia's a leading institute in the areas of prevention, diagnosis and treatment of infectious diseases. Serving the scientific advisory board of the Russian Academy of Sciences and the Russian Ministry of Health and Social Development, Gamaleya

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⁴³⁰ Information based on the U.S. State Department BII website, on the Internet: <u>http://biistate.net/wp/wp-content/uploads/2008/10/biochim.pdf</u> (retrieved 10 August 2009).

coordinates scientific research activities of entities throughout Russia in the field of microbiology. There are nine centres of excellence in brucellosis, tularaemia, leptospirosis, clostridiosis, mycoplasmosis, legionellosis, chlamydiosis, rickettsiosis, and four WHO Collaborating Centres. The Institute's production unit manufactures over 40 immunobiological preparations, including the BCG vaccine for the prevention of tuberculosis.

Gamaleya's activities focus on basic and applied research in the following interrelated areas:

- Medical microbiology, including genetics and molecular biology of pathogens;
- Basic and applied infectious immunology;
- Epidemiology of infectious diseases; and
- Biotechnology.

The Institute works with more than 50 pathogens of bacterial, viral and protozoa aetiology. In accordance with its terms of reference, each centre of the Russian Ministry of Health and Social Development and the WHO maintain a collection of reference and field strains isolated in many geographical regions. A total of 26 laboratory units work with agents of the Group I-II agents, five units with Risk Group III agents (*Fransisella tularensis*, Brucella spp., Rickettsia spp, Botulinum toxin, HIV). The institute has an animal facility and a pilot production plant for veterinary drugs.⁴³¹

Research areas covered:

- Molecular basis of pathogenicity, biofilm formation, mechanisms of apoptosis;
- Immunoregulatory mechanisms;
- Emerging and re-emerging zoonotic infections;
- Computer modelling of epidemics of dangerous infectious diseases;
- Subunit vaccines, including those for tuberculosis and tularaemia prevention;
- New pharmaceuticals with antiviral and immunomodulatory activity for the prevention and treatment of viral diseases;
- Identification of bacterial macromolecules modulating apoptosis of eukaryotic host cells to develop new approaches to the treatment of chronic infectious diseases,
- Ecological, epidemiological and clinical implications of genetic variability of zoonotic infections agents (Brucella, Leptospira, Borrelia, Rickettsia spp.);
- Novel biotechnological methods for the repair of bone tissue, joints hyaline cartilage, tendons and ligaments; and

⁴³¹ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/wp-content/uploads/2008/10/gamaleya.pdf (retrieved 20 February 2009).

 Development of toolkits based on novel approaches for the diagnosis and detection of pathogens.



The Institute of Physiologically Active Compounds of Russian Academy of Science (IPAC RAS)⁴³²

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Website: http://www.ipac.ac.ru/

Research areas

Work is carries out on synthesis and optimization of properties of new biologically active nitrogen- and sulphur-containing heterocycles, phosphorus and organic compounds. Studies are done on the structure and chemical modification of biologically active natural compounds. Studies are carried out of the properties of new functional bioactive nanomaterials (catalysts, sorbents, chelating, means of delivery of physiologically active substances and medicines). Investigations are done on the biological properties of chemicals and mechanisms of their effects on the functioning of biological systems. Testing and screening of new substances to various types of biological activity. Preclinical studies drug candidates for various biological models. Methods are developed for assessing biosafety of new substances, including nanomaterials and biologically active nanopreparations. New immunochemical methods are developed for the analysis of physiologically active substances. Work is done on quantitative analysis of the relationship between structure and activity for a wide range of physiologically active substances.

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⁴³² Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/profiles-of-russian-partner-institutions/center-for-new-medical-technologies-tempo/institute-of-physiologically-active-compounds-ipac (retrieved 10 February 2009).



Research Center for Molecular Diagnostics and Therapy (RCMDT)

Open Joint Stock Company Russian Research Center of Molecular Diagnostics and Therapy (RRCMDT)⁴³³

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RCMDT focuses on molecular medicine including the development of new drugs and vaccines for infectious diseases, as well as studying the molecular mechanisms underlying these new therapies. The Institute employs 77 research staff. 434

Some of the main areas of research are:

- Vaccines and drugs for highly infectious diseases, particularly tuberculosis;
- New generation vaccines based on human dendritic cells and heat shock proteins;
- Immunotherapeutics for tumours associated with Human Papilloma Virus (HPV);
- Study of mechanisms of diabetes and markers of heart muscle pathologies;
- Diagnostics for infectious diseases using monoclonal antibodies and PCR methodology;

⁴³³ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/profiles-of-russian-partner-institutions/center-for-new-medical-technologies-tempo/research-center-for-molecular-diagnostics-and-therapy-rcmdt (retrieved 10 February 2009).

⁴³⁴ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/wp-content/uploads/2008/10/rcmdt.pdf (retrieved 20 February 2009).

- Study of controlled transport of biologically active substances into cells through biological membranes;
- Controlled drug delivery systems using polymer and nanotechnology; and
- Novel biosensors and analytical systems based on scanning microscopy.



State Federal Enterprise for Science Research Center for Toxicology & Hygienic Regulation of Biopreparations (RCT&HRB)

Federal medico-biological agency

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The Center has a well-trained staff of 102, with 77 involved in research. The state institute was established in 1992 and the areas covered by the Center are preclinical trials of immuno-biologicals and pharmaceuticals, as well as toxicology studies of biological and chemical substances through aerogenic exposure of laboratory animals in special dynamic aerosol chambers (there are ten chambers). Tests are carried out of aerosol vaccination methods. The Center also uses molecular-genetic approaches to develop new medical preparations with enhanced therapeutic and prophylactic effects.

⁴³⁵ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/wp-content/uploads/2008/10/rcthrb.pdf (retrieved 20 February 2009).

⁴³⁶ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/profiles-of-russian-partner-institutions/center-for-new-medical-technologies-tempo/state-federal-enterprise-for-science-research-center-for-toxicology-hygienic-regulation-of-biopreparations-rcthrb (retrieved 20 February 2009).

Research areas covered:

- Preclinical trials of novel immunobiological and pharmaceutical preparations, as well as documentation for state registration of these products;
- Toxicological and hygienic standardization of biopreparations for the environment;
- Toxicological and hygienic investigations of biological and chemical substances by inhalation treatment of laboratory animals in special aerosol dynamic chamber facilities;
- Expert assessment of documentation on toxicological regulation of preparations;
- Development of alternate methods in toxicology by using cell and tissue cultures;
- Ecological monitoring and environment protection, including the development of industrial technology for waste processing; and
- Biosecurity.



State Research Institute of Biological Instrument Making (SRIBIM)

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Research and development of novel diagnostics for infectious and somatic diseases using luminescence microassay technology. The Institute has pioneered PHOSPHAN, a biochip technology with a wide range of applications in the detection and quantification of biological molecules. 437

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⁴³⁷ Information based on the U.S. State Department BII website, on the Internet: <u>http://biistate.net/wp/wp-content/uploads/2008/10/sribim.pdf</u> (retrieved 20 February 2009).



Federal State Unitary Research Institute of Highly Pure Biopreparations (SRIHPB)

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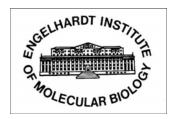
The staff includes 300 biologists, physicists, chemists, physicians, mathematicians and engineers. This facility has been upgraded to comply with international GMP. The research areas covered are novel therapeutics and diagnostics based on immunological principles. Production is carried out of cytokines and peptides of medical interest; novel drug delivery systems; and new adsorption materials for purification of proteins and extracorporeal therapy. Main areas of research:⁴³⁸

- Elucidation of mechanisms of therapeutic activity of endogenous mediators for the development of new biopharmaceuticals;
- Development of new drug delivery systems for targeted and sustained release of drugs;
- Manufacture of drugs, developed in-house, at the Pilot Production facility;
- Manufacture of biopharmaceuticals: recombinant human interleukin-1 β , human erythropoietin, human interferon α -2a, synthetic peptide-based drug for genital Herpes and synthetic peptide-based immunostimulatory drugs. 439

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⁴³⁹ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/wp-content/uploads/2008/10/srihpb1.pdf (retrieved 20 February 2009).

⁴³⁸ Information based on the U.S. State Department BII website, on the Internet: http://biistate.net/wp/profiles-of-russian-partner-institutions/center-for-new-medical-technologies-tempo/state-research-institute-of-highly-pure-biopreparations-srihpb (retrieved 10 August 2009).



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The institute was established in 1957.

Research areas covered:

- Molecular and cell engineering; bioengineering;
- Oncogenomics, oncodiagnostics, oncoprognosis, oncovirology;
- Mobile and repeating genetic elements and their evolution;
- Molecular immunology;
- Biopolymer structure and molecular dynamics;
- The design of new biologically active compounds;
- Genetic enzymology;
- Signal transfer at molecular and cellular level;
- Plant genomics;
- Genomic and proteomic bioinformatics; and
- Study of fundamental principles of molecular/cellular technologies and bionanotechnology.

Russian State Scientific Research Center GNIIgenetika

Director Professor Vladimir Debabov, President of the Russian Biotechnology Academy. The Centre possesses a large collection of industrial microbial strains (over 16 000). It is a leader in fundamental research on genetics and genetic engineering of industrial microorganisms, as well as producing amino acids, vitamins, fodder ingredients, and recombinant proteins.

Research activities cover the mechanisms of the regulation of biosynthesis (e.g. amino acids), gene and operon structures in organisms such as enterobacteria and yeasts, genetic and molecular-biological mechanisms for antigens recognition, and the structure–function relationship of proteins.⁴⁴⁰



State Research Institute of Influenza

The Institute was established in 1967 as the leading institution to control influenza and influenza-like diseases (http://www.influenza.spb.ru). In 1992 it was brought under the supervision of Russian Academy of Medical Sciences.

Under Director Academician Oleg I. Kiselev since 1988, the main objectives of the Institute remain to conduct research on virology and problems of aetiology, diagnostics, epidemiology, clinical characteristics and prophylaxis of influenza and other acute respiratory diseases, and on the development of procedures for their prevention and treatment. Vice-Director Prof. Anna A. Sominina is the head of WHO National Center for Influenza. She is the leader of the National Program of Preparedness to Next Influenza Pandemic and the Plan of Emergency Measures in Case of Pre-Pandemic Situation Development in Russia. 441

Russian-Indian Cooperation

The Integrated Long-Term Programme (ILTP) of cooperation in S&T with Russia is the biggest and most exhaustive scientific collaboration project India has ever entered into. The programme facilitates bilateral cooperation through joint research projects, bilateral workshops/seminars and visits of scientists. The cooperation covers 11 areas related to biotechnology and immunology; biomedical science and technology; ecology and environmental protection; and chemical sciences and life sciences. There are two centres of excellence; one is a polio vaccine production facility, BIBCOL (Bharat Immunological and

⁴⁴¹ University of Turku, ibid. (retrieved 29 October 2009).

⁴⁴⁰ University of Turku, JBL Collaborators, on the Internet: http://www.sci.utu.fi/kemia/tutkimus/orgkemia/jbl/collaborators.html (retrieved 29 October 2000)

Biologicals Corporation Limited) at Bulandshahr. This plant with a capacity of 100 million doses of polio vaccine annually and has received support from Russia. Another is the Indo-Russian Centre for Biotechnology at Allahabad and one Indo-Russian Centre for Biomedical Technology in Thiruvananthapuram, set up[?] in January 2008. 442 443

 $^{^{\}rm 442}$ Indo-Russian Working Group on Science & Technology, Embassy of India, 12 March 2008, on the Internet:

http://indianembassy.ru/cms/index.php?Itemid=520&id=60&option=com_content&task=view (retrieved 20 February 2009).

443 Indian Institute of Information Technology Allahabad, on the Internet:

http://bi.iiita.ac.in/images/BI_IIITA.pdf (retrieved 23 February 2009).

Appendix 4

Acronyms and Abbreviations

API active pharmaceutical ingredient
BfV Bundesamt für Verfassungsschutz
BII U.S. Bio Industry Initiative

BRC Biological Research Centre (OECD)

BSL biosafety levels

BTWC Biological and Toxin Weapons Convention

BW biological weapon

CAGR Compound Annual Growth Rate
CIS Commonwealth of Independent States
CTR Cooperative Threat Reduction Program

DLO Federal Beneficiary Drug Provision Programme

DNA deoxyribonucleic acid DoD U.S. Department of Defense

DQI Directorate of Quarantine Infections EFB European Federation of Biotechnology

ERA European Research Area
ESF European Science Foundation

EU Eurpean Union

FMBA Federal Medical-Biological Agency FAS Federal Anti-Monopoly Service

FASIE Foundation for Assistance to Small Innovative Enterprises

FDA Food and Drug Administration (U.S.)

FGU Federal State Establishment FP Framework Programme (EU R&D)

FSB Federal Security Service

G8 Group of Eight leading industrial countries

Gate2RuBin Gate to Russian Business and Innovation Network

GDP gross domestic product

GKNT State Committee of Science and Technology (in USSR)

GLP Good Laboratory Practice GMP Good Manufacturing Practice

GOSPLAN State Planning Commission of Council of Ministers

ILTP Integrated Long Term Programme

IMD International Institute for Management Development

IPR intellectual property rights ISS International Space Station

ISTC International Science and Technology Centre, Moscow, Russia

IT information technology

ITER International Thermonuclear Experimental Reactor

JSC joint stock company

KGB Committee on State Security
NMR nuclear magnetic resonance
MDR-TB Multidrug resistant tuberculosis

MEDT Ministry of Economic Development and Trade

MIC Military-Industrial Commission

MNTK Interbranch Scientific Technical Complexes (in USSR)

MSED Main Sanitary Epidemiological Directorate

NCP National Contact Point

NPO science production organization (in USSR)

OECD Organisation for Economic Co-operation and Development PCA Partnership and Cooperation Agreement (EU and Russia)

PRC Pushchino Research Centre
R&D research and development
RAS Russian Academy of Sciences

RAMS Russian Academy of Medical Sciences
RFBR Russian Foundation for Basic Research
RFH Russian Foundation for Humanities
RFT Russian Pharmaceutical Technologies
RNCP Russian National Contact Point EU FP7

RTTN Non-profit Partnership Russian Technology Transfer Network

RUSNANO Russian Corporation for Nanotechnologies

RUITC Union of Innovation Technology Centres of Russia

S&T science and technology

SME small and medium-sized enterprise

SPF specific pathogen free SSC State Science Centre SVR Foreign Intelligence Service

TB tuberculosis

UNAIDS United Nations Joint Programme on HIV/AIDS

USSR Union of Soviet Socialist Republics

WTO World Trade Organization

Appendix 5

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