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Realizing Russia's Potential

PHARMACEUTICALS IN RUSSIA: GREAT OPPORTUNITIES

Industry Breakfast

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Moderators:

Vladimir Shipkov, Executive Director, Association of International Pharmaceutical Manufacturers (AIPM)

Vladimir Starodubov, Vice-President, Russian Academy of Medical Sciences\

Panelists:

Jostein Davidsen, Head of Emerging Markets Commercial Operations, Takeda Pharmaceuticals International GmbH

Joseph Jimenez, Chief Executive Officer, Novartis AG

Igor Krylov, Chief Executive Officer and Member the of Board of Directors, JSC Farmstandart

Larisa Popovich, Director, Independent Institute for Social Innovation

Valery Ryazansky, Chairman of the Committee on Social Policy and Healthcare, Council of Federation of the Russian Federation

Sergei Tsyb, Director, Department of Chemical Engineering Complex and Bioengineering Technologies

Vladimir Yablonsky, Director of Social Projects Stream, Agency for Strategic Initiatives

Sergei Yastrebov, Governor of the Yaroslavl Region

V. Shipkov:

The St. Petersburg International Economic Forum presents a unique opportunity for us, and we love any forum that loves us back. Therefore, I hope that what we have in store for us will be a fruitful and effective effort towards the strengthening of Russian healthcare.

I would like to point out the fact that one of Russian President Vladimir Putin's first executive orders was devoted to a set of issues that essentially called for just such a panel discussion as ours today. Furthermore, this executive order and the mandates that followed from it were directed at more than just the executive branch of the federal government, which is collaborating with social and professional associations to present recommendations for organizing a system of pharmaceutical provision and improving the nation's healthcare by the end of this year.

I think that each of us who is present here today, whether we happen to be politicians at the federal level, leaders and high-ranking figures within one of the ministries, representatives of Russian or foreign companies, or experts from an institute of the Academy of Sciences, and so on, we are all participants in this process. I am very pleased to see in our audience government officials from both the federal and regional levels.

Yesterday we heard a very promising statement from the Russian President, who said that there will doubtless be an improvement in Russia's investment climate. A business ombudsman was announced yesterday, which is also a very important step in this direction.

The Government of the Russian Federation is also announcing a new policy of increased openness, which has already shown results. Just this week, I have already sat in on one of the special discussion sessions of the Government of the Russian Federation, which, of course, we applaud.

The new Minister of Health Veronika Skvortsova has also declared publicly that the Ministry will become increasingly open to constructive dialogue with professional associations, experts, and others.

By the same token, I would like to add that we have before us a unique opportunity to engage in dialogue with practically everyone from the President to the Minister of Health, who recently confirmed to me her readiness not only to communicate, but also to consult with the professional community and market players in working out the best policy for the system of healthcare and pharmaceutical provision. That is why we should view the order of the President of the Russian Federation as being addressed also to us, and maybe to us as much as to anyone else.

It could be said that we have tried to recruit a special edition of the *Rossiyskaya Gazeta* to our endeavours. Please note the special section called 'Pharmaceuticals'. This is an official government programme devoted to this event. This is the third year that we have put together this industry event, and I would like to believe that this is not just an episode in the history of the Forum, but rather a tradition through which we will produce results.

I want to thank the organizers and all of the participants who have found time to come here. It is a great honour for me – I cannot even describe the feeling – to hand the microphone over to someone whom I would call a guru of Russian healthcare, and of healthcare in general. This man is a veritable encyclopaedia of theory and practice, and probably the biggest expert in the field of healthcare management. Allow me to introduce Vladimir Starodubov, Vice-President of the Russian Academy of Medical Sciences.

Mr. Starodubov, the floor is yours.

V. Starodubov:

Thank you, Mr. Shipkov.

Ladies and gentlemen, esteemed colleagues, I would like to begin by thanking the organizers for the opportunity to present at such a distinguished gathering. I am truly no expert in the pharmaceutical arena, and have spent my whole adult life working in healthcare administration. But attempting to organize healthcare in the absence of the pharmaceutical element becomes rather problematic. That is why I agreed to be one of the moderators of this Forum. By way of introduction, I would

like to point out that recently we have seen the creation of a regulatory structure for healthcare. Three fundamental laws have been passed in the last few years. One is ‘On the Circulation of Pharmaceuticals’, which, granted, already needs serious reforms, but these are already in the works. Another is ‘On Compulsory Health Insurance’ (which is also in need of some amendments), and finally ‘On the Foundations of Healthcare for Citizens of the Russian Federation’. This law only came into effect on January 1, and we are now discussing various issues of implementation.

Why am I talking about the regulatory structure? Because the regulatory structure creates an environment within the country that allows us to move forward in certain directions. One part of this is the notion of standards which is at work in these laws, and which serves as a powerful lever within the pharmaceutical marketplace. Which drugs will be approved, and what kinds of testing will be required by these standards? These decisions will be based upon the expertise of the medical community. The conditions which are put forward through this process will determine the quality of care provided to our patients. That is why the standards of medical treatment that are due to take effect on January 1, 2013 are currently the biggest headache for healthcare administrators.

This headache could, of course, be passed on to the pharmaceutical community, which is why we are all interested in ensuring that the standards are more or less acceptable. They must be based on empirical medicine and they must serve as a guarantee of the quality of medical care. This is the triad of problems we face today. We will encounter a great deal of difficulty, but we must nevertheless solve these problems if we wish to implement these standards.

The next issue which I would like to raise relates our capacity to improve the demographic situation in the country. This situation has, in fact, been getting better in recent years. One of the ways to do this is, of course, through preventive care and a growing awareness of various aspects of healthy living. This is obviously problem number one, and success in solving it brings very tangible results. For every rouble invested in preventive care, experts say, there is a four-rouble return

on investment. The next most pressing problem, I would say, is the issue of pharmaceutical dispensation for out-patient treatment.

In 2011 (and I am taking these numbers from memory, so I might not get them all right) expenses on healthcare in the Russian Federation added up to RUB 1.75 trillion. Out of these funds, RUB 750 billion were within the health insurance system, of which roughly RUB 90 billion came from voluntary health insurance and RUB 604 billion from compulsory medical insurance. The share of these expenses taken up by pharmaceuticals, by various estimates, makes up about RUB 468 billion. These are the prices given by manufacturers.

Why have I cited these numbers? According to expert opinion, in order for us to achieve substantive improvement in medical care and in demographic indicators (which include not only infant and premature mortality but also quality of life), if we are to see positive results in these areas, experts suggest that the Russian pharmaceuticals market needs to grow by a factor of five or six by 2020. Compared to countries with comparable purchasing power, our expenditures significantly lag behind not only the OECD countries, but also the newest members of the EU. Here we have vast reserves, which we see based on the fact that we must implement (I chose my words carefully here) a system of pharmaceutical dispensation for out-patient care. This is not simply a matter of the indicators for which constituent entities of the Russian Federation are responsible; it is also related to people being able to avoid having to be hospitalized simply in order to receive free medications. This is a massive area for the healthcare system itself, for substantive changes in the conditions which confront our patients when they decide to seek in-patient or hospital care.

Within this sector, we can see that out of the resources which I have mentioned, roughly RUB 282 billion are engaged in the retail sector. Another small segment, about RUB 48 billion, is in the hospital sector, and about RUB 78 billion is accounted for by government purchases from the federal and regional budgets. We can see from the comparison of these funds that our prospects for implementing

out-patient dispensation of drugs face some serious challenges. The legislative framework must make progress in this direction.

I have carefully avoided using the term ‘prescription drug insurance’, even though ultimately it should be prescription drug insurance that serves the population. I will cite just two more statistics so as not to bore you too much. We have made projections with regard to a specific cardiovascular pathology. In order to achieve 100% indemnity for out-patient prescription drug treatment for children, and 50% for the adult population, we would have to spend about RUB 200 billion. The minimum economic effect of implementing this insurance would be RUB 900 billion. Therefore, in terms of healthcare administration, we can certainly justify rallying behind the cause of diverting more of the country's resources, especially since our average life expectancy is still well below the level we are aiming for. We have a great deal to do, and I invite you to discuss these issues at today's Forum.

I have not talked about the investment climate, nor about the groundwork that has been done in various constituent entities of the Russian Federation. In recent years we have seen regions aggressively developing pharmaceutical clusters. These include St. Petersburg, the hosts of the Forum, as well as Yaroslavl Region, Kaluga Region, Sverdlovsk Region, and many other regions which have given this issue their utmost attention. Of course, the task of the executive branch is to create a microclimate that would attract investors, allowing them to comfortably and profitably develop projects which they have already begun to implement. Thank you.

V. Shipkov:

Thank you, Mr. Starodubov. You are completely right to begin by highlighting the importance of the regulatory framework to the current situation.

I would like to bring to the attention of the audience the fact that our breakfast is being attended by two chairs of special committees of the State Duma. Participating in our panel are Sergei Kalashnikov and Valery Ryazansky, who represents the Federation Council. So I think that your suggestions have been heard, Mr.

Starodubov, and that we are fated to work together to perfect the regulatory framework.

Colleagues, I saw how sympathetic Ms. Popovich was to your plight, and how she checked your facts regarding the numbers. Perhaps you could now share with us your thoughts, Ms. Popovich? And maybe you could also tell us how accurately Mr. Starodubov remembered the statistics, which you are also working with.

Ladies and gentlemen, the Director of the Institute for Social Innovation at the Higher School of Economics, Larisa Popovich. Welcome!

L. Popovich:

Director of the Institute for Health Economics would be a more accurate job title for me.

Mr. Starodubov is, as always, exceptionally precise and positive in his assessments. Therefore, I will start from a slightly different angle. Indeed, Russia's entry into the OECD will lead to more detailed scrutiny of Russia's healthcare system. The indicators we are talking about – those small positive indicators which one can begin to observe in Russia – will unfortunately begin to be compared with other indicators. In our community of experts, it would probably be best to avoid talking about achievements, and talk about more serious matters. If we do not focus on the major problems, it is unlikely that we will solve them.

And our problems are rather serious. I gave a talk at the Adam Smith Forum, and showed these charts. The statistics on the health of Russia's population, given the fact that we spend, to put it crudely, more than USD 1000 per person, are about equivalent to countries spending USD 170.

Yes, unfortunately, we often talk about the ineffectiveness of our healthcare system, and we can also speak volumes about the causes of this. These include the lack of focus within our health services, a slightly skewed choice of priorities, and an absence of macroeconomic assessment in our decision-making process. Mr. Starodubov has shown you the relative statistics involved in treating diseases. The numbers I presented are different. RUB 24 billion invested in the fight against drug

addiction yield RUB 400 billion in savings across society. What I am getting at is that we need to make a general transition toward using macroeconomic data in our decision making in areas like healthcare. First and foremost, we must identify those pressure points of investment which will have the greatest effect on the whole healthcare system. It goes without saying that access to prescription drugs is one of these pressure points.

If we go ahead and compare ourselves to other OECD countries, we see that their patients spend about 40% of the sum total of the money that goes toward their healthcare on accessing prescription drugs. The patient himself spends 40% of the money on pharmaceuticals. In Russia, patient spending accounted for 83.5% of out-patient costs, according to last year's numbers. In total, 69% of all drug costs within the healthcare system are borne by the patient out of their own pocket.

I am extremely concerned about the fact that despite the rise in incidence of disease, the consumption of medications has basically plateaued in real terms, rising only in monetary terms. This speaks to a very serious lack of access to pharmaceutical treatment for the population. Certainly, as I have said numerous times, showing the correlations, our government spends far less on providing access to drugs through the public sector: it spends 6.67% of what Germany spends, to put it bluntly. Whereas our per capita GDP is only half that of Germany.

When we talk about a new system of pharmaceutical dispensation, we must never forget about the three demands placed on any government authority that has to make decisions on changes to the pharmaceutical dispensation system. We have a mandate to give the population access to prescription drugs, but at the same time we must take into account the efficacy of any government spending, as well as concerns about the safety of various drugs.

A system of reimbursement or insurance for prescription drugs is a good model. But having worked on this issue for many years, I also understand all of the risks which await us when we implement this system. There are three reasons that will make it difficult to implement this system in the Russian Federation. These three reasons correspond to the patient, the doctor, and the system. A patient might act

irresponsibly with regard to his own health, maybe they are not taking enough medicine, or they might simply fail to carry out a doctor's instructions. A doctor may be uninterested in the outcomes of his practice. And the system may not be ready for change. These three serious problems would be detrimental to the prognosis for a successful implementation of prescription drug insurance.

But there are three factors which, in the absence of an implementation of prescription drug insurance and an increase in access to prescription drugs, could prevent us from moving our population towards better health. These three factors are the patient, the doctor, and the system. There are serious issues surrounding the current health of our population, the need to increase the level of training for doctors, and the need to improve the efficiency of the few resources which are currently tied up in the healthcare system. We simply have no other options for raising the efficiency of our healthcare system other than to quickly implement prescription drug insurance.

What are the benefits of a system of prescription drug insurance? Of course, access is one of them. First and foremost, there is an increase in the quality of patient care. In addition, there is a system of prescription drug insurance that will provide a flexible, precise mechanism for prescribing drugs to fit the specific needs of patients. It will allow us to overcome rigidity and the limited set of prescription options. It is precisely in the context of a system of prescription drug insurance that we will be able to create a flexible system of price regulation, and move away from the archaic system of controls that exists currently.

And finally, perhaps the most interesting angle here is the chance to promote Russian manufacturing, which is indeed very important. It will be possible to set up the whole system of referential pricing so as to benefit domestic production.

V. Shipkov:

Perhaps we can now turn directly to a domestic manufacturer for comment?

L. Popovich:

We will give him the floor. I just have one more thing that I would like to add. Clearly, the main problem at the core of the system of prescription drug coverage, which we will have to take into account as we plan the implementation, will be the incorporation of mechanisms to counteract spending. Ultimately, this is the locus of the greatest risk in implementing the system. We have to find mechanisms that will not break apart the system and will preserve it in a governable and effective form. I see this as a very important topic for discussion.

V. Shipkov:

Thank you, Ms. Popovich.

I would like to move next to Igor Krylov, who represents one of the most dynamic domestic companies, and is one of the leaders of our drug manufacturing community. Please go ahead, Mr. Krylov.

V. Starodubov:

Esteemed colleagues, since we have a number of people who wish to speak, please limit yourselves to three to five minutes.

I. Krylov:

To begin with, I would like to sincerely thank all of the members of the AIPM Association, and Vladimir in particular for inviting me.

Esteemed colleagues, as I am a representative of the domestic pharmaceutical industry, and we are here with representatives of the executive branch, as well as the legislative branch, I would like to draw our attention to another matter which could help us to lighten the burden – the financial burden, first and foremost. This is the issue of responsible self-medication.

To my great personal dismay, the current law boils down to an initiative that would ban over-the-counter medicines, which would entail a massive budgetary burden and make it impossible for more than 60 million people to get medical treatment.

The term ‘responsible self-medication’ was first heard in the 1980s. Data from clinical studies shows that the United States saves USD 120 billion per year, with 60 million Americans using responsible self-medication. A high percentage of responsible self-medication as a way for people to care for themselves is used both in developing and developed countries. The percentage of self-medication is as high as 33% in the United States, and 28% in Great Britain. This is a very significant portion of the healthcare system. That is why we should look very carefully at this sector, since clinical studies in the global self-medication industry (which are available) show that ten years of advertising for OTC products increases the use of OTC medicines by 2%, while the prescription rates of prescription drugs grows by 20%. In the US economy, every dollar spent by a patient on behind-the-counter or over-the-counter medicines yields six dollars for the economy.

I would suggest treating this issue very seriously. Since Russia is moving toward a system of universal healthcare, specifically pharmaceutical care, we should pay close attention to this element, which will allow us to reach the goals set by the President. As a representative of domestic manufacturing, I am proud that Mr. Putin first announced plans for 100% prescription drug coverage while on a visit to our factory in Kursk four years ago. The pessimists have, to put it mildly, a very tense relationship with this goal. I am an optimist. I believe it can happen, and since the time of the announcement necessary steps have been taken. A list of critical medicines has been created and updated. A registration process has been created. Whatever we may think of it, it allows us to register the prices of critical medicines. The point made by Mr. Starodubov earlier was that we are still waiting for a set of standards. Indeed, this was put on hold for a year or two. But we hope that the ‘Law on the Foundations of Healthcare for Citizens of the Russian Federation’ will begin to enforce standards starting next year. Once we have standards of treatment, once we have set prices and a specific list of drugs, then we can establish a budget. As our Minister, Ms. Skvortsova, has said, in 2015–2016 we will launch a pilot programme. I hope that that happens, and I would add that responsible self-

medication as a part of maintaining personal health is a significant aspect of healthcare.

I have been given five minutes, and there are two minutes remaining.

Colleagues, I would like to speak now on behalf of the industry, simply as a manufacturer. We are faced with some serious problems at the moment. For the members of AIPM these are not as acute, since for the moment they do not produce as much within the Russian Federation. But the situation today is completely nonsensical. We do not register our active pharmaceutical ingredients. We can have them in the drug registry as a completed pharmaceutical product, but then we must pay 17% VAT to import them. We have petitioned the Ministry of Health, the professional ministry of our industry several times. We ask that this question be straightened out. As per the Law on the Circulation of Medicines, we no longer receive a certificate of registration, but customs law still requires that 17% VAT. This puts a serious burden on manufacturers, and we would like to see a recalculation of the VAT, since it is contrary to the current legislation. That is the first problem.

A basic problem common to all of us, in my view, is the absence of an arbitration process for those seeking to register a drug, in cases where they disagree with the result. This has an impact on all of us. This kind of arbitration process must be instituted. As we know, in the earlier system, the work of the filer and the work of the expert evaluator combined to create the basis for the new drug. Complicated drugs require complicated methodologies. Evaluators used to visit manufacturing sites and give input into methodologies. Today, this is impossible, and that is why we ask that the process be harmonized. The registration process suffers as a result of the current situation.

I will go on to the next problem. The registration process lacks an opportunity to submit additional evidence and documentation of new, developing circumstances. The process is such that we submit instructions for a product for review before we conduct clinical trials. Clinical trials then reveal new information. The current procedure does not allow us to submit additional material. We ask that this also be reconsidered.

Finally, there is the issue of clinical practice. The problem is that under current legislation, the initiating company and the sponsor of clinical trials are not allowed to pay an honorarium to the research physician. Our payments always go directly to the medical institution. This leads, from a legal point of view, to the complete detachment of the physician from the results of his or her clinical study. International clinical practice, on the other hand, includes direct payment to research physicians as well as payment to the clinic. This could restore the direct responsibility of a doctor for the quality of his study and for its results.

These are, to my mind, the concrete problems that most urgently require resolution. Solutions to these problems will yield concrete results.

Thank you very much for the opportunity to speak.

V. Shipkov:

Thank you, Igor.

From the audience:

Mr. Krylov, the last issue will be problematic, since it will not pass the anticorruption test with regard to the doctor himself.

I. Krylov:

We have compiled extensive literature on this subject, and we do not see an element of corruption here. The expenses of the institution are covered by a contract with the institution, and the direct honorarium of the research physician comes out of a contract with the research physician. The company declares the sum being paid, and declares the services rendered.

V. Shipkov:

Mr. Krylov, for my part, I would like to present to you the commentaries of the Institute of Legislation and Comparative Law under the Government of the Russian Federation. There you will find approaches to solving this problem. But in any event,

thank you so much for putting forward these problems, which are indeed difficult. These are the things that keep us up at night, and we must seek to create coalitions in defence of the correct positions.

Esteemed colleagues, I wanted to inform you all that parallel to our breakfast, there is also a meeting of the President's Foreign Investment Advisory Council, and some of the guests we have scheduled to speak at our breakfast will arrive later. But I can assure you that the CEO of Novartis will be joining us.

I will now give the floor to another representative of the international pharmaceutical industry, a man who has given more than twenty years of his life to working for Soviet and Russian healthcare, among other things. This is a man who loves Russia, who works hard for Russia and for Russian patients, that is, for you and me. Three years ago, speaking here on behalf of AIPM, on St. Petersburg soil, he surprised everyone by announcing that members of the Association are prepared, in the near future, to invest up to USD 1 billion. He became a leading example for the early stages of localizing manufacturing processes within the Russian Federation, a veritable locomotive for the industry.

I give the floor to the Vice-Chair of the Board of Directors of AIPM, as well as the Chief Operations Officer and Vice-President of Nycomed-Takeda, Mr. Jostein Davidsen.

The floor is yours. Please.

J. Davidsen:

Spasibo, Vladimir. Two years ago at SPIEF I brought the president of Nycomed at that time to St. Petersburg for this breakfast meeting. That was the first time it was organized. I introduced him to the Minister of Industry and Trade at that time, and I said to him, "May I introduce you to Mr. Björklund, the president of Nycomed? I would like to explain that we have decided to invest EUR 80 million in a pharmaceutical plant in Yaroslavl." The answer was, "Mr. Davidsen, why so little?" Our president was a bit shocked at that comment. I actually thought it was a joke, and I still assume it was a joke. An investment of EUR 80 million does not sound

very big compared with many other industries' investments in this country, but for a pharmaceutical industry it is quite substantial.

I work today in Takeda and I believe that one of the main reasons why Takeda acquired Nycomed in October 2011 was basically because of what we had created in the emerging market, and especially what we had created here in Russia. I strongly believe that this is an example of an investment success story that basically indicates that you can make very good investments in Russia, and you can have a very good return on your investments in Russia. Takeda is 230 years old, and it is still called Nycomed Takeda here in Russia, but slowly and gradually, it will be moved into a Takeda company as time passes. I work today with emerging markets and I sometimes call them 'emergency' markets. These markets are not stable. It is up and down. You see volatility, you see compliance issues, and it is a different framework to work with compared with Europe and the United States. You all know this. There are similarities, however. I just came back from Brazil two weeks ago. We made an acquisition in Sao Paulo, and there is a lot of similarity there to the Russian market. It is a retail market and a generic market, and there are strong local manufacturing companies in Brazil. There is a lack of reimbursement, or the reimbursement is just in the introduction phase. It is very much commodity-driven and market-driven there, and is dependent on growth.

There is a lot of similarity with what you see in Russia. If you look at Russia, Brazil, and India today, and if you look at it a little bit in retrospect over the last five years, you see a very impressive growth in euro value. India has grown over the last five years from EUR 3.9 to 7.9 billion in value. Brazil has gone from EUR 7.8 to 15.7 billion in value, and Russia from EUR 6.2 to 10.2 billion in value from 2006 to 2011. It is a substantial marketplace for all of you who are doing business in this part of the world. I strongly believe that the main contributors to the global pharma market going forward will come from these markets, and Russia is definitely one of the key markets playing a role here. If you look at the main factors in these impressive dynamics and growths, it is GDP growth, it is increasing wealth, and in parallel to basically increasing imports, you also see increases in local production, which is

very much increasing as well in these markets. Having been around now for the last eight months in all these emerging markets, of course this is the market I love most, and this is the market I strongly believe to have one of the biggest potentials for growth. It is definitely still today the most profitable marketplace among all emerging markets, at least in our portfolio and in our business. We should not forget that.

I will mention briefly about seven or eight key points that are important in Russia at this moment in the healthcare and pharmaceutical industries. The government has a strategic objective for the country to increase health expenditure from 3.8% to 5.5% over the coming years. That is critically important. Just remember that increase from 3.8% to 5.5% if that happens. That is a substantial value increase in healthcare expenditure in this country. If you look back to 2005 – many of you were active in 2005, at least with the international community – you will see all the initiatives that have taken place from 2005 until today. I will just mention the National Healthcare Project, the DLO, the 2020 Project, obligatory medical insurance, and so on. This country and this government have not been sleeping since 2005. You can see clear trends and clear directions where the country is going in terms of healthcare strategy, and you do not see that in every emerging market around the world. One of the key decisions we are taking in 2011 is to increase insurance payments up to 5.1%. The plan with that is a RUB 460 billion accumulated increase, which is equivalent to about RUB 10 billion over the next year. This is substantial. This will gradually improve standards in the country, and it will boost the market, but more importantly, it will give patients access and availability. We have to understand what that means. It will make the state the primary buyer in the market going forward, and this is very much a swift change compared to the last 10, 15, or 20 years since the collapse of Soviet Union, where Russia has basically been out of the public market place.

We all talk about reimbursement. I know that the Ministry of Healthcare has a pilot project on reimbursement that they want to kick off in 2014, and that this is supposed to be assessed by 2016. We are all very much looking forward to it, and we are all excited about what it will turn into. This is definitely the key driver for the

growth of the market. It is the key for the accessibility of good, innovative medicine for the patients who need it throughout the whole country. There are a lot of ‘ifs’ for that to happen, however. I have spoken about the macroeconomy, which is a key factor here basically to make this reimbursement system come out in real life.

I have a few words to say about the pharmaceutical industry. If you look back three to five years – you can only go back three years given what has happened during this period of time – you will see that there have been a lot of concrete actions. We have been moving from talks to actions in the last three years. We see about 10 international pharmaceutical companies setting up their facilities, going into R&D collaboration and innovation, joining forces with Russian companies, etc. A lot of effort has been made to move on in terms of localization and innovation. Takeda is opening its plants. We are integrating the EUR 80 million investment in Yaroslavl in September 2012. We are also focusing on educational projects, and we established an innovation centre two years ago to go along the path of basically where the country should go. Finally, I will say one thing, and this is really what I mean to say. The key success factor would be to bring Russian-invented products and Russian-manufactured products from ideas to patients. Thank you.

V. Shipkov:

Thank you, Jostein.

Thank you. Now, with great pleasure, I give the floor to a new institute which has recently appeared in our country. This is Vladimir Yablonsky of the Agency for Strategic Initiatives.

V. Yablonsky:

Good morning, esteemed colleagues.

I have been asked to say a few words about our agency. I believe you already know that we were created at the initiative of Vladimir Putin one year ago. I will proceed to the results we have achieved, so as not to dwell on history. Yesterday's statements by the President touched on the investment climate, on roadmaps, 100 steps – and

not for the first time. This is one of the results of the Agency's work so far: a national initiative for entrepreneurship and improvement of the investment climate.

How does our agency function? Our original mandate was to become a platform for communication with business – a platform of communication with society – and to work out what obstacles there are to investment and growth of business, and to discover what is preventing the average citizen from actively developing civic initiatives, especially within the middle class. This is our target audience, the middle class, and medium-sized business. Here we find the cause of people moving away, of the failure to realize projects.

The primary mission of the Agency is, indeed, to facilitate communication. The process of developing the roadmaps that the President talked about yesterday is an example of our work. We have launched crowdsourcing projects and set up expert working groups in order to help develop these roadmaps in collaboration with business. This is probably the first time that business and bureaucracy have collaborated on working through ideas for legislative change in our country.

I think it is very important that in the introduction to the President's executive order, the structures behind prescription drug provision are mandated to be developed in dialogue with social organizations. I think that the agency and the social movement which I am representing will participate directly in this process.

I would just like to add a few more words about our methodology. Our Agency has received proposals for more than three thousand different projects. They involve both business and social initiatives. We put these projects through a selection process, seeing what kinds of regulatory obstacles can be found, and work with various federal offices to assist them in overcoming these obstacles in an expedited manner.

I would like to give a few examples of projects we have already supported. With us in the audience are representatives of R-Pharm. We have already pushed through the Agency’s Supervisory Board, which is headed by Mr. Putin, a project to create an Academy of Biotech Industry on the basis of the Tomsk Polytechnic University. This project has already been approved by the agency and is being implemented.

There are a few other examples of successful projects. Our Expert Council has already approved a project, which is now being looked at by other experts, for a medical cluster in the Greater Moscow area. This will be a Russian-German medical university and a full-service clinic, with private investment of up to USD 1 billion. They plan to attract more than 200 faculty members from abroad, both for teaching at the university and for strictly medical work. This entails a whole series of problems which must be overcome. These include permission for specialists from abroad to engage in clinical practice, as well as a dual certification for graduates, who will receive both European and Russian diplomas, and so forth. We see these kinds of projects as being of utmost importance, because they truly represent an opportunity to transfer technology and human resources to the Russian Federation.

We are working on several other projects to connect business with social services. They involve the healthcare sector, as well as other social sectors, such as high-tech support, and are granted on a competitive basis.

I would like to give another example of a project which is perhaps unusual for our sensibilities, but which nevertheless fits with the theme of today's breakfast. Our Expert Council looked at this project just two years ago. It was one of our Agency's debut projects. This project is based on traditional medicine, on questions stemming from Eastern medicine. The project was to emulate the Japanese model of a third category of medicines: traditional medicines which could be sold over the counter and in a simplified form.

To give you an idea of the way we work, I will add another example of a project we have launched. On the May 3, we came before Mr. Putin's Supervisory Board to confirm a whole new programme for giving business access to develop a private sector in preschool education. As you all know, Russia has nearly two million children on waiting lists for kindergarten, and the Government cannot keep up with the demand. Just in the Greater Moscow Region, there are 150,000 children on waiting lists. We developed a series of regulations for allowing business to enter into this sector.

There is another aspect of our work that I would like to highlight. Currently, we are working with Opora Russia to promote an initiative called ‘Russia: Land of Health’. This will be a multifaceted initiative which deals, again, with giving small and medium-sized business (and, in fact, big business also) access to various segments of the healthcare market. These include medical services which are now provided by the state. June 26 will be the first meeting of the working group. I invite all of you to participate, and can provide information, which is also on the Agency's website.

We are incredibly pleased to see discussions at today's Forum about the investment climate and about a new dialogue between government, business, and society. The questions which have been broached today are key to the quick resolution of problems and to speedy progress. Our agency was created for just such a dialogue, and we are open to all proposals. We are ready to share our experience in quickly moving forward with initiatives, and can help you communicate with government offices, civic organizations, and the various structures and regional authorities of our nation which are ready to get to work. Thank you very much.

V. Shipkov:

Mr. Yablonsky, I am grateful to you for informing us about your agency. Here is my card; we are also open to collaboration with you and others. Thank you very much.

And now, ladies and gentlemen, as promised, we have been joined by Joseph Jimenez, CEO of Novartis, who has just come from a session of the Foreign Investment Advisory Council. Joseph, the floor is yours.

J. Jimenez:

Good morning. I would like to make a few comments about Novartis’ participation in healthcare here in Russia. Specifically, Novartis welcomes the government’s efforts to improve overall healthcare in Russia, including increasing life expectancy, increasing regulatory transparency, and the modernization of the pharmaceutical industry here in Russia. We support the President’s ambition to improve health, focusing on three areas: cardiovascular disease, oncology, and tuberculosis, which

are all stated goals. We strongly support President Putin's very encouraging request to have the national strategy for drug provision in place by next year. This would be a breakthrough in Russian social policy. It could significantly increase the affordability of medicines for Russians everywhere in the country, and it would provide a framework for reimbursement and future drug insurance coverage. As one of the largest healthcare companies in Russia, we are making a commitment to invest significantly further in the country. We have made a commitment of investing about USD 500 million incrementally over the next few years. A big part of that investment is our pharmaceutical facility that is being built right here, outside of St. Petersburg. This will produce many of the Novartis innovation drugs, and also generics, and over-the-counter drugs that are sold here in Russia. We are not just investing in infrastructure. We are also investing in research and development collaboration with many of the universities in the country, and this is one thing that we see as very important in terms of knowledge transfer about drug discovery, drug development, and helping to build the pharmaceutical industry here in the country. We are investing significantly in public health programmes in some of the regions. Specifically, can we help the governments within Russia deliver on Health 2020, improving life expectancy, and reducing mortality and morbidity for many diseases, specifically cardiovascular disease? We have a number of programmes going on right now, and we expect to increase those in the years ahead. Novartis is committed to working with Russia, the Ministry of Healthcare, and the Association to expand a national reimbursement system, which we think will be critical and will be very good for patients in Russia, aligning clinical trial administration with international standards, developing a clear biosimilars regulatory pathway – which will also become critically important as some of the biologics lose patent protection over the next few years – strengthening IT enforcement, and strengthening GMP standards throughout the country from a manufacturing standpoint, so that we can instil confidence among the population in Russia in very high-quality pharmaceuticals including innovative products, generics, vaccines and over-the-counter drugs. Thank you very much.

V. Starodubov:

I should point out that Novartis is deeply involved in the Russian product market, and is one of the leaders in terms of volume of product sold in our segment of the market. Their level of investments, not only in manufacturing, but also in new innovations, is obviously very pleasing to us. This shows the serious relationship the firm has with the Russian market. We thank you.

It is a great pleasure to give the floor to the Governor of Yaroslavl Region, Sergei Yastrebov. This region stands out as one of the leaders in pioneering the pharmaceutical cluster system. Even though Mr. Yastrebov has only been Governor for a short time, he knows Yaroslavl Region inside and out, and these issues are second nature to him. Thank you for your support, Mr. Yastrebov.

S. Yastrebov:

Ladies and gentlemen, I am so very pleased to be here with you all and to represent Yaroslavl Region, which has managed to secure a fairly stable process for the development of a pharmaceutical cluster in collaboration with some of the world's leading companies. Just now we heard the esteemed representative from Novartis, with which we have a close relationship in our efforts to optimize our region's systems of cardiology and internal medicine. We have had some notable successes in our efforts. Last year, mortality in our region fell by 9%. Interestingly, that 9% came out of our cardiology patients. So we have had a small but very noteworthy success.

Yaroslavl's pharmaceutical programme has been developing for four years, and it is very important that we have been able to show results. We have been able to convince companies, both at home and abroad, of the benefits of our region's highly developed logistical infrastructure. In our case, the interests of private enterprise and government have coincided, and we hope to achieve great things. We can already show the results of our work, results that one can actually sense. With us today is Alexey Repik, who collaborated with us last year in opening a factory, and

we are now preparing to build and open the second stage of the project. We have also collaborated on a large scale with Nycomed-Takeda. Jostein was a bit too humble in his presentation. In September, we will celebrate the conclusion of our work on building these facilities, and we hope to begin production and take the next steps going forward. We have worked just as closely with Teva, and just last week we finished a major set of negotiations. We held our discussions in Yaroslavl, and the representatives of Teva are also with us today. We have agreed to break ground on that factory in September. The first tranche will be small, about two billion pills, but God willing, if all goes well, we will be able to increase output to eight billion. In theory, this will give the Yaroslavl cluster a fairly prominent position on the prescription drug market in the Russian Federation. We are hoping for a 15% market share. In any event, my Government colleagues and I have always provided and will seek to provide the best conditions for our partners. We truly do see the companies involved in our pharmaceutical cluster as our partners. I am confident that today's discussion and our proven track record will entice new companies to come and set up shop in Yaroslavl Region. We welcome you! Thanks for your attention.

V. Starodubov:

Mr. Yastrebov, since you have a pharmaceutical cluster in your region, perhaps we can also launch a pilot programme for prescription drug insurance in Yaroslavl Region?

S. Yastrebov:

If you entrust us with this task, we will take up the challenge with pleasure. Thank you, Mr. Starodubov.

V. Starodubov:

Thank you, Mr. Yastrebov.

Esteemed colleagues, I now have the pleasure of giving the floor to Sergey Tsyb, the champion of pharmaceutical manufacturing at the Ministry of Industry and Trade.

S. Tsyb:

Mr. Starodubov, Mr. Shipkov, and esteemed colleagues, it is a great honour to be with you today and to give a short presentation. I did not plan on addressing you today.

Practically all of the largest pharmaceutical companies are represented here at this breakfast. It is already becoming a tradition to gather here, at one of our country's most important events, the St. Petersburg International Economic Forum.

If you would allow me, I would like to touch on two things which I have been able to observe. I got back from Boston two days ago, where we had the second opening of a Russian pavilion at the BIO International Convention 2012. I see this as an important event in the history of Russian pharmaceuticals, given the trends through which our country is moving towards international integration. Our entry into the OECD in 2014, plus membership in the WTO and many other international initiatives, will doubtlessly solidify many processes, including the development of high-tech sectors. This applies not only to the Russian Federation. I believe that this trend towards international integration will take root in many countries with developing economies and developing markets. But I would even suggest augmenting this terminology by moving away from the notion of ‘developing markets’ in favour of ‘high-growth markets’. So my observation is the following: we have a huge problem with awareness. It seems to me that all of the initiatives which we have tried to move forward in the last three years unfortunately dissolve in a sort of information vacuum, even in our own country. That is why I claim it is necessary to create new initiatives so that we can stimulate the Russian companies and research institutions that are involved in drug development and joint business ventures to be more active in the information arena. These are simple steps that need to be taken. Websites of all companies and institutions should be readable in

English. I have personally witnessed many complaints from people about how they simply cannot understand what is happening over here, and do not know what initiatives and new laws are being launched to stimulate growth in this sector of the Russian economy. That is why I think information and public relations should be at the top of the agenda, especially given the active international collaboration which we have been witnessing in recent years. We see the entry of large foreign companies into the Russian market, already going beyond simply the realm of sales, and moving into concrete cooperative ventures in manufacturing and research projects. I think that in the near future, we will need to have a primary focus on informing our colleagues about the need for good information channels.

The second thing to which I would like to draw your attention is the issue of education and human resources. Here, I think, we also need to consider additional measures and new initiatives which would allow us to actively develop human resource potential within Russia to provide the industry with good professionals. These new cadres must have a new attitude, a new way of thinking, and they will be part of a whole new generation in regard to international cooperation and the integration of Russia into the global market. In any case, the global division of labour will call for us to find our niche within many high-tech industries. But that will require literate, highly trained professionals who will be able to commercialize all of the current projects being undertaken by academia and business. I think that the initiatives created by foreign companies, which are actively approaching us with educational ventures for the Russian Federation, as well as joint ventures, are very significant, and important for the development of this sector.

The last thing I want to say is that the emergence of joint R&D ventures in the Russian Federation is a very positive trend. Between Boston and here in St. Petersburg we see the conclusion of contracts in this sector especially. Whereas two or three years ago we saw companies beginning to actively invest in the manufacturing sector, now we already have many companies announcing joint ventures. In my view, this is also exactly the right kind of trend, given that the global pharmaceutical industry is basing itself on innovation. We must move in the

direction of these innovations and develop this sphere as aggressively as possible. We are supporting this as part of our Federal Target Programme, and it is pleasing to see that our targeted programme already has many examples of successful technology transfers. The government has entered jointly with Russian companies as an investor into international ventures for drug development. I will refrain from listing the companies, but they are all well-known names, and it is very pleasing to see these kinds of projects materialize. We hope that they are successful. I wish all of you much productive work and many interesting meetings. It is a great pleasure to see you all, and best wishes to all. Thank you.

V. Shipkov:

Thank you very much, Mr. Tsyb. Is Nikolay Savchuk with us? He had asked to say a few words. Mr. Savchuk, just a couple of minutes, since we are already a bit pressed for time. The name of Mr. Savchuk's firm is ChemRar. We have a very large market specifically in biological drugs, and Mr. Tsyb has said that this is one sector where we must reclaim our positions, because a new immunization schedule is coming online. We will work toward expediting this and introducing those drugs which are recommended by the WHO.

N. Savchuk:

I will just make a few comments about what has been discussed by the moderators and the esteemed representatives of the Government and the pharmaceutical industry.

First, I will say a few words about cooperation. Our country's policies for the development of the domestic market are very good ones, and will be a long-term factor in the economy. The most important aspect of these policies is that they are a two-way street. Besides doing their own R&D, Russian companies engage in R&D in collaboration with multinational pharmaceutical companies. Multinational pharmaceutical companies can have a very significant effect on the development of standards for good laboratory practice and good manufacturing practice, and this

process has already begun. Pharmaceutical companies are involved in these projects in conjunction with Institute of Pharmacology, and collaborate on these projects with their R&D partners. We have seen these kinds of projects come out of Novartis as well as Pfizer, for example. Pharmaceutical companies are taking a role in education, which is especially important to the partners involved in joint investments. Today, Johnson & Johnson is announcing a partnership with Skolkovo and ChemRar to form a venture project, which will invest in early rounds of funding for biotech start-ups in Russia. These companies represent a very important sector to Russia: the creation of new types of drugs, and the use of existing commercial products as a foundation for new types of products. This is a very important trend, since Russian healthcare can be a resource for the economical creation of new drugs on the basis of existing ones. These basic trends, it seems, can be extrapolated from what our colleagues have just outlined for us. Thank you.

V. Shipkov:

Thank you, Mr. Savchuk.

Esteemed colleagues, we are pressed for time. We are already being told to wrap up. Mr. Starodubov, speaking from your experience, from the trends and processes that you are witness to, what can you tell us in conclusion? What ideas can the transcript of our discussion pass on to our new Minister of Health, our Minister of Trade, and other interested offices in the government? Please, the floor is yours.

V. Starodubov:

Colleagues, in my meeting with the Minister we touched on many topics, including that of the pharmaceutical market, and I think we have much cause for optimism.

I remember, in the middle of the 2000s, when we began a programme which produced the Seven Nosologies programme. For Seven Nosologies, which had a budget of RUB 33 billion in 2008, I believe we received a bid from one domestically produced drug made by Farmstandart. This was a growth hormone, I think, and so at first, the share of Russian-produced drugs was RUB 100 million out of RUB 33

billion. But when companies saw that this was a stable, long-term programme, then local manufacturing began to rise by factors, even orders of magnitude.

That is why I think that our bright future lies in the Government's ability to use certain mechanisms, and not just its own resources, to guarantee consumption of drugs by the population. That is, they will guarantee that these drugs will be paid for. I will reiterate that the expert consensus is that the Russian market today is very undersaturated with pharmaceutical products. This is not because that they are not available here, but because the population does not yet have sufficient means. But as life expectancy grows, consumption of medicines will also grow. I will repeat the statistic again: if a one-time estimate of the market in Russia today comes to RUB 11–12 billion, then by 2020 it will grow to USD 75 billion. These are the opportunities that are in front of us. That is why I expect the Government to create an investment climate conducive to providing the population access to reasonably priced prescription drugs. If this comes about, then pharmaceutical manufacturing also has a bright future. Thank you very much.

V. Shipkov:

Thanks to all of you, esteemed colleagues. We hope to meet you back here next year, in the halls of the St. Petersburg International Economic Forum. In the meantime, I have a suggestion for an intermediate meeting place; let me know what you think of this, Mr. Starodubov. In October, the annual European Health Forum will be held in Gastein. Maybe we can have a discussion there about what we will have accomplished between now and October?

V. Starodubov:

Yes, there is a European forum which takes place under the aegis of the WHO’s Regional Office for Europe. It is a meeting of healthcare administrators, pharmaceutical companies, and various experts. The Forum will be in early October.

I have one more little note to add. The institute at which I am the Director has already developed a legislative project which touches on the issue of collaboration among pharmaceutical companies. The law is about prescription drug insurance in the Russian Federation, and we have done calculations to determine the resources needed to implement it. Now we need boots on the ground to run localized experiments that will allow us to extend this to the entirety of the Russian Federation. Thank you.