

RUSSIAN PHARMACEUTICAL REVIEW



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ON THE BACKGROUND OF THE GLOBAL ECONOMY'S WORST YEAR SINCE 1946, the recent Economist Pharma Summit in London focused on emerging markets for growth with Mr. Robin Bew, Chief Economist at the Economist Intelligence Unit, predicting that for Russia and Ukraine "seismic economic change will fundamentally reshape society". Yet as the longer-term trends reassert themselves after recovery in 2011 and beyond, Russia will remain a strategic market for companies like Astellas, and Nycomed, which have shown resilience in the tumultuous 1990s to capitalize on the last eight years of growth and emerge well-placed to weather this economic storm. Quote of the day at the Economist Pharma Summit goes to Dr. Richard Barker, Director-General of the Association of the British Pharmaceutical Industry, who recently met a representative from the Russian Foreign Service and asked him how he saw the future of Russia - the answer was straightforward: "Tell me the oil price."

In the first of a series of exclusive interviews with senior pharmaceutical executives I ask Mr. Jostein Davidsen, General Manager of Nycomed Russia/CIS, for his perspectives on a diverse range of subjects including market access, the economic outlook, and how Nycomed is building for the future through large-scale capital investing in Russia.

Gerhard Symons
Editor

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Russia's reckoning: *The Economist* Pharma Summit

Agility and innovation in emerging markets were the themes discussed in context of the financial crisis, which was synthesized by Mr. Robin Bew, Chief Economist at the Economist Intelligence Unit, in a frenetic 30-minute journey around the world at *The Economist* Pharma Summit. According to Mr. Bew, 2009 is a year of reckoning for emerging markets, in particular for Russia, which is suffering from lower inward investment and aggressive borrowing from international markets, despite a reasonably well-balanced budget. "2009 will be extraordinarily difficult", said Mr. Bew, with 2010 being better – however recovery will be seen further out – partly because experts do not see the decoupling of the developing world with the developed world.

Yet Mr. Bew's analysis is not all bad news – the emerging world post credit-crunch will become even more important than today as the financial centre of gravity moves from Europe to Asia, and emerging markets grow at the expense of the EU/Japan. By 2025 the global demand for goods and services will be dominated by Asia with the other emerging economies remaining a 'side-show' in the bigger story,


although East Europe is predicted to have a larger share of global GDP than Latin America. As growth is predicated on a growing population and increasing productivity, Russia must reverse the demographic downturn to participate in the wealth creation of the future. There is solace for the pharmaceutical industry in

2009 will be extraordinarily difficult

that long-term trends forecast higher private spending in Russia, but, as Mr. Bew pointed out, growth does not equal scale.

In a session dedicated to exploring business models for emerging markets, Mr. Ken Jones, Chief Operating Officer at Astellas Pharma Europe, had much to say about Astellas' experiences in Russia. For Astellas, Russia is a semi-mature European market – not quite European Big Five (UK, Germany, France, Italy, Spain), but not wholly emerging either; and on in which they entered in 1990. Astellas weathered the 1998 ruble crash by staying in the market and by taking a radical step – managers and staff took a 50 per cent pay cut. Since

those days, the organisation has slowly increased its field sales force to 300 and dealt with all the minutiae of operating a sales force across multiple time-zones, for example, managing network access, and managing a fleet of cars – with Mr. Jones making the observation that the Toyota Corolla is the most robust vehicle for Russia's varied terrain. The result is that today, Astellas Russia is a large organization with experience, and is Astellas Europe's fourth-largest affiliate.

Considering Russia, with the economy as it is and the historical capriciousness of her political masters, one delegate asked how carefully political risks were assessed in emerging markets? Mr. Jones was unequivocal: "Very carefully – you have to [assess the risks] – as it's a rollercoaster ride. When petrol is US\$150 – fantastic, but when it's US\$30, [the Russian Government] can't afford to enlarge access." Mr. Jones' advice comes from years of experience operating in unpredictable markets: "You have to keep your ears close to the ground, and the organization has to react [to Government demands] – that happens quite a lot." 

The Economist Pharma Summit

12 February 2009
Renaissance Chancery Court Hotel, London

Speaker highlights: Alan Mackay, 3i; Ken Jones, Astellas;
Richard Barker, ABPI.

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RosZdravNadzor chief slams judicial system

In an outspoken interview Dr. Nikolai Iurgel', Director of The Federal Service for Surveillance in Healthcare (RosZdravNadzor; РосЗдравНадзор), criticised the efficiency of courts in prosecuting counterfeit cases, exposed instances of corruption within the judicial system, and pointed out fundamental inadequacies of current legislature. The interview, published in daily broadsheet *Rossiiskaia Gazeta* (*Российская Газета*), follows publication of RosZdravNadzor's 2008 inspectorate activities, in which it was revealed that the number of counterfeit batches seized by RosZdravNadzor doubled in 2008 compared to 2007, and that the number of counterfeited drug trademarks increased by 30 per cent over the same period.

In 2008 RosZdravNadzor seized a total of 1,074 batches of counterfeit drugs, comprising 406 different drug trademarks. Of the total batches seized, 653 (60.8 per cent) were from domestic manufacturers, and 421 (39.2 per cent) were imported drugs. RosZdravNadzor has also been monitoring manufacturing quality, confiscating 187 batches of six up-stream pharmaceutical ingredients, and seizing 1,190 batches of finished drugs produced from unregulated pharmaceutical ingredients. This is a strategic move to adopt international standards in drug quality monitoring, as Dr. Iurgel' explains: "The focus will shift from checking the quality of finished drugs to ensuring that drugs are produced under appropriate conditions."

Dr. Iurgel' revealed widespread abuse in the supply chain across Russia: in one-third of Russian regions, inspectors found 62 warehouses with large quantities of drugs whose addresses did not match with their

licensing documents. In addition, these firms evade taxes, and use unregulated pharmaceutical ingredients to manufacture counterfeit medicines, according to Dr. Iurgel'. In a bold disclosure, Dr. Iurgel' cited the case of Farmasintez (Фармасинтез) in Irkutsk, which officially purchased 8.5 tonnes of pharmaceutical ingredients from an Indian supplier, although it was found to have actually purchased 24 tonnes, with a value of R532m (US\$15.2m). Unusually, this firm is alleged to have produced an anti-tubercular treatment of unverified composition, which despite not being registered with Federal authorities, was on the list of life-saving medicines and thus reimbursed by Irkutsk Oblast'. Once RosZdravNadzor investigated this case, the regional Court of Arbitration fined Farmsintez R40,000 (US\$1,150), and during legal proceedings Farmsintez requested a licence renewal from RosZdravNadzor, which was summarily declined. In a farcical turn of events, Farmsintez lodged an appeal with the Moscow Court of Arbitration which ruled that RosZdravNadzor had behaved inappropriately, and that it had to renew the licence.

Dr. Iurgel' said this was not an isolated incident: "Each year about one hundred criminal cases are lodged and a few hundred civil cases are opened but only a small fraction of them receive a verdict, for example, in 2008 only 30 licences were canceled. Evidently, the courts cannot process documents within the necessary timeframe, specified in Russian law and RosZdravNadzor itself does not have the necessary authority to impose any sanctions." While current legal code still has many exploitable loop-holes, there are no specific articles intended to

deal with counterfeit medicines and health supplements – moreover, complained Dr. Iurgel', "counterfeit drugs found during inspections can not be used as evidence in court."

Yet, Dr. Iurgel' is optimistic about working with Olga

RosZdravNadzor itself does not have the necessary authority to impose any sanctions.

Borzova, Chairman of the Duma Committee for Health Protection, to increase RosZdravNadzor's authority to impose fines which are proportionate to the value of the counterfeit drugs seized, and to consider imprisonment as a sanction of last resort. As reported in *Russian Pharmaceutical Review* in January 2009, the committee is dedicated to restricting the flow of counterfeit and low-quality medicines in Russia, and to raise the level of the national pharmaceutical industry to international standards.

With that last aim in mind, RosZdravNadzor sent an official delegation to the FDA in January 2009 to discuss a range of issues including; regulating production and licensing of drugs; strategies to fight dissemination of counterfeit drugs; and training of specialists to participate in collaborative programmes. In the first of its kind, delegation members met Harvey Feinberg, Director of the National Institute of Health (NIH), and Frank Torti, acting FDA Director. Importantly, this meeting established a commitment to sign a memorandum of mutual understanding and cooperation between RosZdravNadzor and the FDA, which is expected to be signed in Moscow later this year. 

Medicine pack price to rise 20 per cent

The steady depreciation of the ruble against the dollar in the last few months is having a significant impact on the price of medicines in Russia, whose average pack price is predicted to rise by 20 per cent H1 2009, according to Moscow-based market research group DSM, and reported in economic daily broadsheet *Kommersant* (*Коммерсант*). The ruble depreciation is affecting imported medicines, as well as domestic manufactured medicines, whose manufacturers are reliant on active pharmaceutical ingredients imports.

There are concerns that the rising prices for medicines might lead to a shortage of drugs in the DLO (Medicines Reimbursement; *Д о п о л н и т е л ь н о е* *Л е к а р с т в е н н о е* *О б е с п е ч е н и е*) programme, however officials at The Federal Service for Surveillance in Healthcare (RosZdravNadzor; *Р о с З д р а в Н а д з о р*), maintain that many auctions for supplying DLO-reimbursed medicines in Q1 2009, happened in Q4 2008. The issue is that last year's auctions were set in rubles, and conducted on a background of a falling ruble value. Unsurprisingly, the Government is putting pressure on distributors to honour

the contracts, which require distributors to purchase drugs at today's unfavourable rates, but to sell drugs to pharmacies and to be reimbursed at last year's price point.

Under these conditions the risk is that many distributors may decide that the deal is too unprofitable, however there is a third way, according to Mr. Getman, a former advisor to RosZdravNadzor. In daily newspaper *Vremia Novostei* (*Время Новостей*) Mr. Getman suggested that Government again negotiates with foreign pharmaceutical companies to lower drug prices, saying "in my experience foreign pharmaceutical companies never directly refuse to negotiate but it may cause considerable delay with drug delivery."

With access to healthcare being a priority for many Russians, politicians have started to voice their concerns, including Dr. Tatiana Iakovleva, Deputy Head of the ruling United Russia party (*Единая Россия*), and a member of the Duma Committee for Health Protection, saying "currently there is no system in place to monitor drug prices on a regular basis". A Press statement from Dr. Iakovleva's office states

that foreign manufacturers have taken advantage of the current situation to ramp up drug prices, claiming that the price of an imported medicine in Russia is considerably higher than the equivalent price in the country of origin. Dr. Iakovleva proposes

in my experience foreign pharmaceutical companies never directly refuse to negotiate...

to counter this by tightening the control that the FAS (Federal Antitrust Service; *Ф е д е р а л ь н а я* *А н т и м о н о п о л ь н а я* *С л у ж б а*) exercises over drug prices.

In reaction to the ruble depreciation, and in a bid to appease pharmaceutical distributors and to protect consumers' interests, RosZdravNadzor issued a decree № 01И-25/09 on the currency of price caps for drugs on the Life-saving and Essential Medicines list (*ZhNVLS; Ж и з н е н н о* *Н е о б х о д и м ы е* *и* *В а ж н е й ш и е* *Л е к а р с т в е н н ы е* *С р е д с т в а*). From 26 January 2009, price caps will be set in a foreign currency for foreign manufacturers and in rubles for domestic manufacturers. 

Sources: *Kommersant*, 20 January; *DSM Website*, January 2009; *RosBalt*, 22 January 2009; *Vremia Novostei*, 13 January 2009.

EXECUTIVES

A busy week for **Tatiana Golikova**, Minister of Health, who was appointed Chairman of the Committee for Prophylaxis, Diagnosis and Progression of HIV, and confirmed as Chairman of the Federal Fund of Mandatory Health Insurance (FFOMS; *Ф е д е р а л ь н ы й* *Ф о н д* *О б я з а т е л ь н о г о* *М е д и ц и н с к о г о* *С т р а х о в а н и я*) by Prime Minister Vladimir Putin.

Changes at CEE firms as **Anastasia Antonenkova** becomes General Manager of Polish Medicines (*П о л ь с к и е* *Л е к а р с т в а*), and **Ishtvan Chaki** is appointed General Manager of Gedeon Richter in Russia.

Promotion for **Grigorii Kokhraidze**, who is appointed Vice-President Medical and Social Programmes at Rosta Pharmaceuticals (*Р о с т а*).

Paediatric care under spotlight


Three themes of unequal access to high-technology treatments, problems in orphan drug legislation, and inadequate palliative care for terminally-ill children were discussed at a joint Press conference by RosZdravNadzor, the Federal Centre for Paediatric Haematology, and the childrens' charity 'Give Life'.

Despite a MinZdrav (Ministry of Health; Минздрав) decree of 29 December 2008 (786-н), giving local departments and ministries a right to request necessary treatment for children, the quota system in place has not been equitable, according to Dr. Valentina Shirokova, Director of the Department for the Development of Medical Aid to Children and of Maternity Care Services at RosZdravNadzor, adding: "In 2008, 2,776 children received high-tech medicines at Federal clinics, and in 2009 MinZdrav allocated 4,216 quotas – of which 1,342 quotas were for regional clinics, and 2,726 to Federal clinics."

According to 'Give Life', children from dozens of regions in Russia cannot access innovative chemotherapy, radiotherapy treatments, or bone marrow transplants which are only available in clinics in Moscow and St. Petersburg. Moreover, due to the high costs of imported medicines, doctors in the regions are using Russian and Indian generics more and more - generics which have not been tested in clinical trials in Federal centres, argued Dr. Galina Novichkova, Director of the Federal Centre for Paediatric Haematology. Dr. Shirokova acknowledged that authorities have not properly allocated quotas, but that they are addressing the issue, adding that parents could now go straight to the Department of High-tech Medical Aid to receive a medicines quota from a floating reserve.

'Give Life' considers current orphan drug legislation problematic in that many orphan drugs are unregistered in Russia

because they are unprofitable for distributors to stock. Family members have to procure drugs for orphan diseases from overseas and pay 30 per cent in taxes and tariffs to transport them across the border, claimed Professor Aleksei Maschan, Deputy Director of the Federal Centre for Paediatric Haematology. However, he suggested a solution: "the problem could be solved through automatic registration of orphan drugs in Russia, which have already been registered in the European Union."

The third problem outlined by 'Give Life' was the absence of any network of childrens' hospices in Russia – where even Belarus, with a population of 10 million, had seven childrens' hospices. Moreover, it was claimed that regional doctors have a deficiency in anaesthesia and palliative care, the solution of which would be to pass a law on palliative care to ensure adequate treatment and care. 

Funding of 'Health Concept 2020' in doubt

In a television broadcast Tatiana Golikova, Minister for Health, reassured viewers that funding for the National Health Project up to 2011 would not be affected by the global economic crises. There remains a question mark over the funding of the Health Development Concept 2020, described in Russian Pharmaceutical Review in February 2009 as a new healthcare initiative. Mrs. Golikova went on to say that "we may not be able attain the desired goals for funding of the Health Development Concept 2020 as quickly as we had planned."

In the same broadcast Mr. Dmitrii Borisov, Executive Director of 'Equal Right to Life' – a non-profit organization - voiced

the opinion that even the National Health Project might not be able to deliver care to patients because of rising drug costs, adding: "it is unlikely that the passed budget will be sufficient to cover rising expenses. Without additional funding, the fight to save lives of critically ill patients, who could be saved if treated with effective medicines, will become a losing battle."

Despite concerns for the funding of the two big Federal health programmes, National Priority Health, and Health Development Concept 2020, project financing for the Pharmaceutical Industry Strategy 2020 might be accelerated due to the global financial crises,

according to Dr. Sergei Tsib, Director of the Department of Chemical and Bioengineering Technologies. In a Press statement from MinPromTorg (Ministry of Industry and Trade; Минпромторг), Dr. Tsib confirmed that architects of the strategy – such as the newly-appointed Andrei Mladentsev, Director of the Institute of Applied Innovative Research, and Andrei Ivashenko, Chairman of the Board at XimRar - met with representatives from the Ministries of Finance, and Economic Development, to review a draft version of the strategy. 

Government commits R26bn to oncology

Speaking at the second annual forum of the patient advocacy group 'Movement against Cancer' (Движение против Рака), Mrs. Elena Telnova, Deputy Director of The Federal Service for Surveillance in Healthcare (RosZdravNadzor; Росздравнадзор), announced that R26bn (US\$722m) had been ear-marked for the Oncology Programme from 1 January 2009 until 2015 to cover capital equipment and medical costs, with R6.3bn (US\$175m) allocated for this year alone.


Mrs. Telnova explained that funds for oncology drugs are channelled through the ONLS programme (Provision of Essential Medicines; Обеспечение Необходимыми Лекарственными Средствами). ONLS is a sub-programme of the DLO, and is funded at the regional level, however access criteria still apply – patients must have disabled status, and there are regional variations in the provision of drugs, contingent on regional drug reimbursement

lists. For patients, there is a lack of information on which funds are available, and for whom. Mrs. Telnova cited a recent poll showing that a half of respondents think that oncology patients do not have access to the necessary drugs, and one-third think that patients have to pay for the drugs themselves.

Funding has not been allocated to meet patient needs as Mrs. Telnova herself revealed: "one of the problems encountered is that there is no detailed cancer patient registry, which is necessary to calculate the amount of required medicines. In some regions, cancer registries were created as late as in 2008, so we do not have the whole picture."

The programme will be rolled out step-wise across Russia's administrative regions from 2009 to 2015, explained Mrs. Olga Krivonos, Director of the Department of Medical Aid and Healthcare Development at MinZdrav (Ministry of Health; Минздравсоцразвития). "Ten regions will be covered this year,

with a further 37 regions enrolled by 2012, plus Moscow and St. Petersburg cities. The remaining 34 regions will be enrolled by the end of the programme in 2015" said Mrs. Krivonos, adding that for entry to the scheme, the 83 regions will each have to guarantee that they will provide the funds, upon which they will be eligible for Federal budget subsidies.

Mrs. Krivonos cited the latest epidemiological data, showing that 480,000 cases of newly diagnosed cancer were registered in 2007, and that 2.5m Russians were undergoing treatment at cancer centres. Furthermore only 43 per cent of patients survived beyond five years of diagnosis, and 300,000 Russians die from cancer annually. One of the metrics of success expected from the programme will be an observed decrease in overall annual cancer mortality from 201 per 100,000 population to 193.2 per 100,000 population, 2012. 

Sources: 'Ten national RF subjects are included in the National Oncology Programme', Ami-Tess, 5 February 2009; 'Elena Telnova: In Europe, €40-200 are spent per patient per year on oncology drugs – in Russia €4', Ami-Tass, 4 February 2009.

ECONOMICS

Russia GDP e2009 [% change from 2008]

+1.0*; -2.2**

Source: *The Economist February 21 2009; **Ministry of Economy, RF

Crude Oil Price

US\$41.63 per barrel, Russia Urals 32°

Source: 20 February 2009, Energy Information Administration

Currency

US\$1.00 = R36.1

EU€1.00 = R45.7

GB£1.00 = R50.8

Source: 1 March 2009, www.xe.com

PASSIONATE VETERAN: NYCOMED'S JOSTEIN DAVIDSEN

Gerhard Symons interviews Jostein Davidsen, Senior Vice-President Nycomed Group, and General Director, Nycomed Russia-CIS.

GS: You've been in Russia for a long time - what did you do in your early career?

JD: I graduated from business school in 1985 and I started work for the Norwegian Trade Office in Dusseldorf, Germany, for two years, assisting Norwegian companies doing business in Germany. In 1987 I started in Nycomed, Oslo. At that time I was in charge of the contrast media business, first in Eastern Europe, and later on in the Soviet Union – so I've been working in this territory for

almost 20 years. For a two year period in 1992-1993, I was based in Vienna setting up the Eastern Europe office and then I moved to Russia in January 1994. I've been here ever since then and today I also have responsibility for the CIS markets too.

GS: What was the market like then when you came?

JD: In the early 90s, when the Soviet Union collapsed, the market was relatively small – you never knew what it was going to lead

to, and you were unsure about the development. It was an extremely emerging market place – actually it was a wild jungle! Everything was starting up from scratch and

It was an extremely emerging market place – actually it was a wild jungle!

from the early 90s to the mid 90s, the market was modest.

In the mid-90s, everyone was starting to come in – the big-multinationals. In 1997 – the peak year before the crisis in 1998 – everyone saw the start of the direction of the marketplace – but it was a market without any substance at that time. There were more than 4,000 distributors in Russia in 1997, but most were unreliable, without substance. When the crisis came in 1998/99, with the ruble devaluation – by 350 per cent if I'm not mistaken – it was a crash, and the market started to rebuild itself and it has been a very healthy turnabout from 2000 up to today. Just now with the financial crisis, Russia is starting to face the impact in our industry as well.

GS: How has the portfolio changed, and the marketing to support it?

JD: We started immediately in the early 1990s to penetrate the regions by establishing our subsidiary in 1992 and we were already in Siberia, St. Petersburg, the Urals, etc. We didn't know exactly how it would work, but we started to hire people. At that time we had mostly generics – plain and branded – and we had all the products that we had sold in the Soviet Union, so the product portfolio was very particular to Russia. In 1995-96, we streamlined the portfolio more and more – to have fewer generics and to build up the portfolio.

GS: ...and why was that?

JD: Due to the low-price local manufacturers and Indian products. We saw the market developing into a new era, and we decided to build the future with a portfolio that we could grow. We have always had a philosophy that we are here for the long-term, and to have a strong presence, so we need a return on our business. If you look today, about 45 per cent of Nycomed

Box 1. Nycomed in Russia

Nycomed punches well above its weight in Russia – for a company in the global pharma top 30, it has a 2.62 per cent market share of the value of pharmaceuticals in Russia, ranked in seventh place in the commercial market, ahead of Gedeon Richter, GlaxoSmithKline and Solvay Pharma, according to RMBC Retail and Hospital Audit data. Moreover, Nycomed Russia/CIS is the fastest growing region for the group, with sales up 23 per cent (in €) in 2008, compared to 2007 (full year results). Russia/CIS accounts for about 10 per cent of net turnover in 2008, which was €3.4bn.

Although the company was founded in 1874, operations began in the Soviet Union in 1987 with the establishment of a subsidiary in 1992.

products sold in Russia/CIS are in-licensed products for which we have exclusive distribution in this region. For the last six years we have been very strongly focussed on dedicated business development in Russia/CIS, and we have been very successful in terms of this. This success is based on exclusive distribution with partners today, such as Merck KGA, GE Medical, Chiesi, Almirall, and Biogen Idec – with highly innovative products.

We are very ambitious and we are hungry to attract new business.

GS: ...and how much business comes from Russia versus CIS?

JD: Russia absolutely dominates with roughly 70-75 per cent of total revenues. Ukraine and Kazakhstan are equal as number two. (See Box 1.)

GS: What do you offer partners in the region compared to your competitors?

JD: First of all we have a very good track record, so it is easier to attract new business. Secondly, we

have a very good infrastructure, and we are based in 121 cities in all the key regions with a very dedicated and dynamic sales force which is large – between 600 and 700 representatives in Russia, and a large sales force in Ukraine and Kazakhstan too.

We are diversified, so we are not only specialised in only one or two areas – we are strong in neurology, cardiology, osteoporosis, and OTC products – 30 per cent of revenues come from the OTC business. We are very ambitious and we are hungry to attract new business. Our partners feel that Nycomed Group has a market focus – it is a strategic market, we are here long term, there is a solid organisation in place, and we have been here 20 years if you include the Soviet time. I set up the business here, and that means something – having good know-how and experience in the market. Finally, we understand that compliance and ethics are extremely important and partners find that Nycomed is aligned with their expectations in these terms.

GS: You raise an important point about business conduct - what was your contribution to the AIPM code of practice which came out last year?

JD: All members of the AIPM signed up to this code of ethics and it was a very good achievement. I've been on the Board of Directors of the AIPM for ten years, and I have seen a great improvement in how to do business, how to advertise, how to do marketing, compared to five, ten years ago.

GS: What are your thoughts on the AIPM's success in negotiating with Government, for example with DLO debt repayments?

JD: When the DLO was introduced in 2005 it came from thin air – it was a case of 'you have to implement the DLO tomorrow, because this is the plan.' At that time we had just five or six weeks to conclude contracts with distributors before the new year, and we had to get these contracts in legal compliance

We have no interest in collapsing, and we need to sustain development.

with all the companies. It was very difficult, but we managed as an association to set standards and influence this. The DLO was hardly a success in the first year, because the market increased dramatically and in 2006 the problems came with significant overdue payments to industry. It's difficult to say that the success was just down to the AIPM – I think it was all industry: first of all, distributors took a great interest in this, and there was so much media coverage on the topic itself – basically because it turned into a big problem for patients on long-term treatment who needed products every day. The AIPM played an important role here – we had task forces, credit reports with all the main distributors to see detailed accounts and receivables, and we started very

unified as an association. The AIPM played a very diplomatic role in discussing the serious situation with authorities in 2006 and 2007 and this resolved itself in the first part of 2008 where payment has not been an issue. The AIPM has played a role in many situations where we have had certain new regulations coming which affects the industry, and where rapid action is required. This is happening at the moment with the crisis – we are trying to influence all stakeholders, and we know we are in the same boat and we have to solve the issues together. We have no interest in collapsing, and we need to sustain development.

GS: Did it come as a surprise that the Government imposed a 15 per cent mandatory price cut on foreign medicines for reimbursement?

JD: It was a big surprise for industry to have a 15 per cent premium to locally-manufactured products in terms of participation of tenders. At the end of the day, we have to put ourselves in the shoes of Russian officials. If you read the papers today, food prices are expected to rise 25-45 per cent in supermarkets, because

the ruble has devalued 35 per cent since August/September last year. This is hard for people in an out-of-pocket market - it's a 60% per cent out-of-pocket market – not like Europe with a 80-90 per cent reimbursed market. Russian officials have to attract local manufacturers' attention and support, and it's a protectionist approach. For international companies, defining what is local manufacturing at this moment is part of working in a common, transparent market place - it's a difficult situation.

GS: Where do you place your sales and marketing resources?

JD: Moscow is extremely important and is 27-30 per cent of the total market in Russia, but St.Petersburg, North-West, Ural region – Ekaterinburg, Krasnodar – are also very big regions. We have 10 or 11 regional centres from the Far East to the North West, and we also have cities with just one person, so there is a big spread where we put our resources.

GS: How has the mix of top-management changed since you came to Russia?

Box 2. A blockbuster inheritance?

When Nycomed bought Altana it inherited the clinical programme for Daxas[®] (roflumilast) - a first-in-class oral phosphodiesterase-4 (PDE4) inhibitor for the treatment of chronic obstructive pulmonary disease (COPD). Full data of four pivotal phase 3 clinical trials will be announced later in 2009 with subsequent marketing authorisation filings to the USFDA and EMEA. With blockbuster potential at launch in mature markets from 2010, the mid-term prospects for Daxas[®] in Russia seem less certain partly due to demography, despite the WHO prediction that COPD will be the third leading cause of death worldwide by 2030 – long after patent expiry.

JD: We have a stable Russia/CIS management team, some of whom have been with us for more than 10 years. We also have new-comers – but with significant experience and good professionals. We have several people with international MBAs – very qualified people, and they can be compared to that management level to Western Europe. Most are Russians – if you can still call me an ‘ex-pat’ and not a local! If you take CIS – we have 1,200 people altogether and 800 in Russia, which includes our sales force.

GS: What did the acquisition of Altana bring to the business?

JD: For us, it didn’t bring that much – pantoprazole [GS: Nycomed’s blockbuster PPI antagonist] was not re-registered at this time, so we had to do that ourselves, and we lost a bit of time. The launch of pantoprazole in Russia was at the end of last year. We have a dedicated sales force of 30 people that is in place Q1 2009 and we are very excited about that. There are also some Indian pantoprazole generics – so we will see, its too early to see how this develops, although we are excited about launching it, maybe as an OTC product in Russia? (See Box 2.)

GS: When you re-registered pantoprazole, did you have long negotiations with Government?

JD: Not really - we filed using the reference price in the major European markets. You are free to set a price in Russia, as long as you are not including these products into the essential drug list. If you include this into this life-saving drug list, you would need a reference price from the home country of origin.

GS: What does the promise of Daxas® hold in Russia?

JD: I believe that COPD should be an enormous market in this

Box 3. New manufacturing strategy

The acquisition of Altana meant that the combined operation had a complex manufacturing footprint of 19 plants globally, with overcapacity and redundancy in operations throughout Europe. Three plants in Scandinavia will close, with production to be shifted to plants in Poland and Germany. The rationale for manufacturing in Russia is to supply Russia and CIS only, to support local market activity, and to improve market access in the future. The plant is expected to be on-line by 2014.

part of the world - everybody is smoking it seems. However, the total respiratory segment is about €400m, and COPD is about €25m of that. We are very impressed with the product – it will set new standards, it will raise a positive discussion on the disease itself and we can be an important partner for authorities and for patient associations. But life expectancy in Russia is 57 years for males – one of the lowest in developed countries, and normally you develop COPD when you are in your 50s or 60s.

GS:...with the demographic changes in Russia, do you see COPD becoming even more important in the future?

JD: Absolutely. What I think will become more important in Russia is that we will see a more dedicated spending of resources in disease areas which are similar to Europe’s. We still have to take into account that state-financed healthcare is still below four per cent of GDP, which is extraordinarily low compared to Europe.

GS:...and what are your views on Russia’s short-term economic outlook?

JD: The GDP forecast has been seriously reduced, and the budget is reliant on US\$40 per barrel, compared to US\$100, and money is being used to support the

banks. This is nothing like the ‘98 crisis, but in industry we are starting to see issues in accounts receivables. My personal opinion on market forecast is that there will be a zero growth compared to last year, and it could even be negative growth – perhaps as much as 20 per cent in hard currency - Euros, dollars.

GS:...will all the manufacturers experience that?

JD: Good question. I think so, but the issue is that some companies are very strong in the DLO and State-financed programmes and the State has confirmed very clearly that they will not cut any spend on DLO reimbursement. But with the ruble fall, you have a dramatic and serious value fall.

GS: Are these conditions affecting Nycomed’s plans to set up manufacturing locally?

JD: It is not affecting us at all; any short term measures are not encouraging investment. However any investment decision is for the long-term, not for tomorrow, but for the next five to 15 years. So I don’t think it affects the decision of Nycomed to set up a facility here at all. We are close to deciding the final site, and there are a few sites which we are evaluating and we can make a decision on this perhaps already Q1 2009. (See Box 3.)

GS:...and how encouraging has regional or Federal Government been to attract investment?

JD: At the Federal level in the last two years, it has been modest in trying to attract pharmaceutical foreign investment. What I've experienced visiting all the regions and talking to Governmental administration is that they have been extremely enthusiastic about having us as their partner in that region. And they are doing everything possible to facilitate and promote their region as best they can. There are, to my knowledge, about 20-25 international pharmaceutical companies who are thinking and discussing of investing in Russia and setting up plants. If you calculate that – let's say on average €50-80m per company - that is a €1bn investment if you put all the companies together – and that's a serious amount of money, and a serious question that should be looked at from the authorities' sides and by industry. It will really reshape the GMP quality of drugs in Russia, it will set new standards and help develop Russia into a more transparent marketplace that we would like to see. There are a lot of issues which don't meet our needs: we would like to see infrastructure, roads, electricity, water, and you have to run around many different regions with your consultants looking at all these issues yourself. I've been looking at 20-25 sites, and they are mostly disappointments – inevitably you see just 2 or 3 which are OK to move on with. They are lacking all these basic infrastructure elements necessary - in Russia it takes a long time: to find the site, buying the site – there is an enormous legal framework you need to pass through - Federal, regional licences and all the bureaucracy.

GS:...how do you navigate the system?

JD: Using our experience, qualified consultants, and with the great influence of corporate operations with great experience in setting up factories – and looking at it as how it is. We want a fully-fledged GMP facility and we know that its complicated to do it in Russia – because the infrastructure is not that easy. But OK – we have to say it takes more time, and from the moment we sign the contract on the land, it will take more than five years before we have the first tablets sold in retailers.

GS: What are the issues with GMP in Russia?

JD: There has been a problem - there are factories today with GMP in place, but there is no requirement that you need an FDA or GMP certificate, like we have in Europe today. It has to do with many factors: with history, where the country is coming from, with experience in management, and people. So there are many factors involved. Products manufactured in Russia are mainly generics.

GS: What predictions were made in the early 1990s that have come to pass?

JD: When I was here in the Soviet times, we signed centralised contracts of US\$50m which at



Jostein Davidsen considers manufacturing issues in Russia.

that time was the biggest single contract in the corporation. When the Soviet Union collapsed, and you came into a market place where you had to operate, you always felt it would be an enormous market. Everything is big here – huge! But this can distract you from reality. The country is enormous with 83 regions, but you have to come down a bit to see the realistic picture, and this is what we've been doing. After the crisis in '98, when in '99 we broke even we had a US\$10m business – and this year we have €342m. I told our organisation in 2001 that in five years time we will break the magic US\$100m – nobody believed me, they thought it was crazy – but we reached it in 2002. Its very difficult to set numbers, but I think realistically Nycomed in the CIS region will have a revenue of €1bn in five or six years time.

GS: ...and what are the main drivers for this?

JD: Reimbursement – no doubt it will be the main driver in this part of the world. I think it had a difficult start to organise this in a very complex market-place. Everybody has learned a lot and everybody is keen to work together to establish this. In that respect Nycomed is also changing its strategy moving forward – in terms of building an innovative patent portfolio. In the future we will much less prioritise in-licensing or signing exclusive distribution deals with branded generics. Our focus is on high-technology products that will be included in reimbursement going forward.

GS: Do you envisage reimbursement coming more from regional or Federal sources?

JD: Good question. There has to be a Federal system in place, but I believe that regions play a more important role going forward because they are seriously big. But we see difficulties during the past year or so when this is being established with the DLO.

GS: Speaking to physicians last year many have much more

experience in the West. How does Nycomed work with KOLs in Russia?

JD: Russian KOLs are travelling around, participating in international conferences, multi-

centre clinical trials, sitting as vice-chairs of associations abroad – as in radiology, cardiology. This changes the approach and attitude in the local marketplace for the positive. Doctors in Russia don't have as much time as they had 10 years ago – there are more than 350 pharmaceutical companies on the market – and everybody has huge sales forces going to hospitals promoting products. We are seeing a rapid change here – the doctor is important again in Russia and its starting to be very difficult to hire sales forces who are doctors.

GS: How is direct promotion changing in Russia?

JD: We have about 10 calls per day at Nycomed – and if you


look at Moscow with its terrible traffic – its nearly impossible to keep up with that! In terms of practicalities it's impossible to move. In the regions this is not an issue.

Our focus is on high-technology products that will be included in reimbursement going forward.

GS: How do you work with disparate clinical guidelines?

JD: This is of course a hot topic – and standard of treatment is in a changing process by the authorities. We are waiting for this. I think this is the key – market access will be the most vitally important focus area for pharmaceutical companies moving forward; pharmacoeconomics, pricing, clinical trials, documentation. This will be the valid model moving forward in Russia – I am 100 per cent sure of this.

GS: Jostein, thank you.

JD: Thank you. 

Sources: Author interview with Davidsen, J., 9 February 2009. Telephone, London, UK; Author interview with Björklund, H. 28 January 2009, Zurich, Switzerland; The Nycomed Magazine, Issue 4, Q1 2009. Zurich, Switzerland; Table 3; p. 12. DSM Russia Pharmaceutical Market; January 2009.

CEO Profile

Jostein Davidsen
Senior Vice-President Nycomed Group, and
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Age: 49
Married: Irina, one son.
Born: Bergen, Norway.
Education: MBA, Oslo School of Business and Administration.
Literature: *The Orange Girl*; *Sophie's Choice* by Jostein Gaarder.
Music: Edvard Greig, Bjørn Eidsvåg.
Hobby: Art collecting.
Sport: Skiing, both downhill and cross-country.



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страстью к этой стране,
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Йостайн Давидсен

To be successful in Russia, you need strength
and energy, but moreover passion for the country,
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JOSTEIN DAVIDSEN

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