COUNTRY REPORT

Russia

OVERVIEW

- **GDP**: $1.465tn (2010 est.)
- **% GDP spent on health**: 4.5
- **Country size**: 17,098,242 sq km
- **Population**: 138,739,892 (July 2011 est.)
- **Language**: Russian and numerous minority languages

Source: CIA

AN INTRODUCTION

Russia is the world’s largest country – accounting for 11.5 per cent of the world’s surface – and has a key role to play in the global economy. As the third-largest emitter of greenhouse gases – and also the location of 22 per cent of the world’s undisturbed ecosystems – the country is playing an important role in climate change. It is also contributing significantly to global programmes for health, malaria control, food and energy security, education, financial literacy and agriculture.

As it represents three-quarters of GDP in the CIS, what happens in Russia affects regional economic prospects – and the country is becoming a major provider of development assistance for low-income countries in the region.

The good news is that, according to The World Bank, the Russian Federation emerged from the global recession with lower-than-expected unemployment and poverty. The country’s economy is boosted by high oil prices, but challenges remain in controlling inflation in the short term and in achieving a medium-term shift towards producing a more diverse economy and one significantly less reliant on oil.

According to the World Bank:
- After a 4 per cent growth in 2010, Russia’s real output is expected to grow 4.4 per cent in 2011, increasingly driven by domestic demand
- Consumption growth has been relatively weaker at just 2.1 per cent. This situation may change in 2011: unemployment has been lower than expected, therefore the economy may get an additional boost through more robust, domestic, demand-led growth
- Annual CPI inflation accelerated in January 2011 to 9.6 per cent compared to 8.8 per cent in December 2010
- Unemployment levels declined from the peak of 9.2 per cent in January 2010 to 7.2 per cent in December of the same year; however, in about a third of the regions, unemployment rates averaged above 9 per cent
- Poverty rate decreased to an estimated 12.7 per cent in 2010, down from the actual 13.2 per cent at the end of 2009.

Russia also has to address the efficiency of its public expenditure. According to figures from The World Bank, the country presents significant contrasts in socio-economic, climatic and geographic conditions across its 82 regions. Headcount poverty rates in 2008 ranged from 38 per cent in Kalmykia in the south, to 7.4 per cent in oil-rich Khanty-Mansiysk. In addition, life expectancy for Russian men and women is as much as 14 years lower than their neighbours in Europe. Providing access to social services and infrastructure of comparable quality across this expansive terrain is therefore a key development objective.

Since 2003, Russian authorities, local institutions and international partners have worked together to address the social problems and institutional constraints contributing to Russia’s poor health profile, yielding significant results, particularly in the fight against TB and HIV/AIDS. With support from the World Bank, TB mortality dropped by 18 per cent and the rate of growth of HIV/AIDS prevalence fell by 5 per cent.

As part of the health reform project, pilot regions with 2.5 million people (Chuvash Republic and Voronezh) significantly restructured their health services. The budget share for primary care doubled and access to rural health services and patient satisfaction
improved. In addition, federal regulation of a highly decentralised system became more effective through the adoption of nationwide protocols.

HEALTHCARE PROVISION

The sheer scale of the healthcare provision challenge in Russia is daunting. By landmass, the Russian Federation is the largest country in the world, with about 140 million people. The country has around 600,000 healthcare specialists, including physicians and pharmacists. However, with 40 per cent of these specialists located in the country’s 13 largest cities and supporting less than 20 per cent of the total population (according to estimates based on the 2002 census), it is clear that healthcare provision is highly fragmented.

“The government has embarked upon a number of programmes designed to modernise the healthcare system and assets are being sold to improve the budget”

The healthcare system is state-run and funded, with about 95 per cent of hospitals belonging to the state. However, the system suffers from a chronic lack of funding, with just 4.5 per cent of GDP being allocated to health.

Medical training reform

There is no licensing process for physicians in Russia; the licence is granted to the medical organisation that employs them. Furthermore, the physicians are not responsible for treatment decisions or recommendations, both of which are the reserve and responsibility of the medical organisation.

Doctors are some of the poorest people in Russia – alongside teachers – and often lack good qualifications. There is no incentive to improve qualifications, resulting in out-of-date techniques. As a consequence the nation suffers from a chronic lack of specialists.

The current education system for doctors in Russia is two-tiered: the basic professional qualification takes seven years, this is then supplemented by ongoing post-graduate education which happens every five years. The system is very rigid and there are moves to reform the education process, for example by offering a three- to four-year basic physician qualification to create a general practitioner with the option to continue in education to attain a specialism.

This approach, however, is not supported by the medical fraternity and a more realistic model would be the reform of the ongoing qualification of physicians, evolving from the five-yearly approach to one of continuous professional development, with post-graduate activities taking place annually.

Since January 2011, patients have been able to choose where they are treated, following a change in the law. The state pays and the money follows the patient. However, patients can only permanently change clinic up to November 1 this year, unless they move address.

State system

The Russian healthcare system currently operates at three distinct levels: federal, regional and municipal. The system is fully financially subsidised, with the state providing more than 95 per cent of all hospital financing, including salaries for doctors, nurses and other staff; equipment, technologies and production assets. The system is complex, however, with financing conducted at each of the three distinct levels, and state funding split evenly across federal and regional funds. The system is not vertically integrated and the federal, regional and municipal levels exist in parallel.

Big business has played a part in the financing of the health service, with contributions from leading Russian organisations, including Gazprom, Russian Railways and Lukoil, being reflected at regional level. However, this has created greater fragmentation, with those oil-rich regions having far greater income to support healthcare funding.

In areas where regions rely on state budgets alone, the investment in the health service is lower; many of the hospitals are furnished with outdated equipment and the doctors are poorly qualified and educated. This, combined with lack of experience, hinders the rapid decision-making and innovation required to improve the situation.

Drug funding

In stark contrast to the state-funded health service, up to 70 per cent of pharmaceutical products are financed ‘out of pocket’ by consumers. While the state implements several high-cost programmes for drugs, there is no real reimbursement because insurance companies do not participate in the scheme.

As a result, competition is high among pharma companies, all of which are trying to win a share of the 30 per cent of the market that is state funded. This segment includes high-cost products for the treatment of severe diseases including HIV, TB and cancer.

The Russian government has recently embarked upon a number of programmes designed to modernise the healthcare system. Assets are being sold to improve the healthcare budget, a move that will result in significant privatisation of state hospitals and clinics. In addition, the market regulators are looking closely at standardising the provision of medical and drug services and the Ministry of Health is developing standards for medical treatment through the creation of mandatory care pathways.

“In those areas where regions rely on state budgets alone, the investment in the health service is lower; many hospitals are furnished with outdated equipment...”

Treatment standards

Treatment standards are being developed with a view to unifying all services, both diagnostic and therapeutic, which would be rolled out and adopted across all federal divisions.

These standards are, however, currently only guidance rather than mandatory because the health service still operates across three parallel levels. As a result, the Federal Ministry is developing standards which are recommended to the Regions, while the Regional Ministry of Health builds regional treatment protocols which are recommended to municipalities. Funding differences between the regions continue to promote differences, with those better funded (the oil-rich in particular) undoubtedly taking the lead over other poorer regions.

The creation of standard treatment protocols remains a highly debated issue across Russia. However, standard protocols, which would be obligatory across all regions, are likely to become a reality in the not too distance future. A new law, The Basis of
Healthcare Population Protection, is set to be passed which will regulate the delivery of healthcare and standardise treatment protocols and care delivery.

PHARMACEUTICAL MARKET CHALLENGE
Most multinational pharmaceutical companies have a presence in Russia and consider this market to have good prospects. The market, including taxes and over-the-counter (OTC) products, is valued at around US$17bn in consumer price terms and the compound annual growth rate (CAGR) is estimated at 15-16 per cent until 2015.

There is undoubtedly significant market potential, but companies have many obstacles to overcome before fully reaping the rewards. For most major companies operating in the region, Russia represents less than 1 per cent of global turnover. Getting a foothold in the market is complex and there are a number of procedural anomalies that pose challenges companies do not encounter in Europe. Product registration is essential – a product must be registered in its country of manufacture and pharma companies must undertake clinical trials in Russia before bringing any new product to market.

“The Market access is focused at both regional and local levels to enable pharma companies to maximise opportunities across an incredibly fragmented market”

The 30 per cent state share of the Russian pharmaceutical market is focused on high-cost, innovative drugs and therefore is highly attractive to multinationals. There is no one company dominating this market, however key disease areas such as diabetes, HIV and oncology are not well supported by local providers.

Indeed, the top-selling products are immunomodulators, hepatoprotectors and probiotics, plus the country still has high mortality rates associated with cancer and trauma.

Local versus global
In contrast, local manufacturers produce cheap, but out-dated and often poor quality drugs. It is possibly because of the volume of low-cost drugs that the percentage of counterfeit treatments available in Russia is estimated at just 0.5 per cent.

The poor quality of locally produced drugs is a consequence of the fact that up to 90 per cent of local products are not manufactured under compliance with good manufacturing practice (GMP) standards. The share of local products in value terms is about 25 per cent and by volume (number of packs sold), about 65 per cent. Overall, innovative products command a 20 per cent market share, with traditional drugs claiming another 20 per cent and generics 60 per cent.

Pharma 2020
The state is keen to rebuild the local pharma industry and encourage innovative development. Under its ‘Pharma 2020’ initiative, the goal is that 50 per cent of drugs sold in Russia should be manufactured there. As a result, a large number of multinationals are looking to build manufacturing facilities in Russia – projects already underway include the purchase of Bioton (Polish manufacturer of insulin with local production in Russia) by Sanofi, and there has been activity from Novartis, Nycomed, Novo Nordisk and Berlin-Chemie.

PRICING & REIMBURSEMENT
The Russian pharmaceutical market grew in 2009, primarily due to price increases. Therefore, over the past two years, the state has undertaken a number of initiatives to drive down the price of drugs by 5 per cent. Key to the price reduction was the introduction last year of new price registration for Essential and Vital Drugs (EDL) and approval of regional wholesale and retail mark-ups. While this process was totally transparent, with a clear decision-making structure at federal level, the result was a price freeze, with EDL pricing now based on the lowest prices paid in European reference markets.

It is important for pharma companies to secure a position for key products in either regional or federal reimbursement systems while, given the lack of patient ability to pay, the emphasis will always be on retaining national reimbursement under special programmes.

While this policy has made little impact on prescribing practices at regional and municipal levels, this EDL is expected to form the foundation of a new health insurance system due to be piloted in 2012/2013, which looks set fundamentally to change the way drugs are prescribed and reimbursed across Russia.

In addition to the EDL market segment, there are more than 15 other lists in Russia that limit the activity of pharmaceutical companies. These range from lists of obligatory assortment in pharmacies to the hospital list for drug purchasing and the list of drugs that can be purchased under state programmes.

National reimbursement
Another, increasingly important, trend is the implementation of National Reimbursement. This programme is due to start in 2014, with pilot schemes in several regions being introduced in 2013. Critically for the pharma industry, this innovation is expected to double the volume of the market.

This shift in pricing model will be introduced in tandem with a new emphasis on drug quality. All Russian manufacturers will be compelled to comply with GMP standards by 2014, and this shift is expected to fuel greater growth in the local market. Local providers are expected to deliver new, innovative drugs that are cheaper than foreign imports. Indeed, in many drug classes the substitution of imported drugs will gradually increase.

To support this improvement in local drug quality and innovation, the state is looking to modernise the overall provision of health services across Russia. New standards of treatment are being developed and approved for consistent usage across all regions, while basic medical services will be based on a single standard.

In tandem with the privatisation of healthcare institutions, new laws will allow the patient to choose the doctor and clinic, with reimbursement following the patient. However, while the implementation of the medical insurance system should encourage patients to go to physicians for prescriptions, it is expected that a large proportion of the population will continue to go directly to pharmacies and buy drugs without prescription.

LIMITING PHARMA-HCP INTERACTION
Market access is focused at both regional and local levels to enable pharma companies to maximise opportunities across an incredibly fragmented market. Furthermore, the government is set to pass a law later in 2011 that will limit pharma companies’ access to doctors via medical representatives.

Given that the new legislation would fundamentally change the way drugs are prescribed and reimbursed across Russia, there is a need for pharma to adapt its market access strategies – not least is the requirement to respond to resulting limits the legislation would put on the way companies interact with HCPs.
to doctors, its reps are perceived as the most ethical (see chart, below) with almost 10 per cent of doctors spontaneously ranking Servier reps first on this basis. Servier also heads the rankings on the basis of the quality of the medical information provided (see chart on next page). Novartis is placed second for both characteristics, while KRKA achieves third place on quality of medical information, but only seventh place when it comes to ethical behaviour.

However, the forthcoming legislation, to be discussed again and possibly approved in September 2011, will fundamentally affect the way pharma can interact with HCPs by prohibiting physicians from receiving gifts from companies. This will mean that no money can be offered to physicians except for official clinical studies, post-clinical studies, scientific or pedagogical activities.

Physicians will also be banned from travelling to attend different events organised by pharma: they will not be allowed to receive samples or use products bearing the manufacturer’s logo, but may be able to have a visit from a rep during working hours or at their place of work with special approval.

For pharma this will require a significant shift in thinking. And, unlike other markets where digital marketing is gaining some traction – although it accounts for just 0.9 per cent of global promotional spend – according to experts, just 33 per cent of Russians are

**Emphasis of promotion**

In Russia, the most widely used channel for product promotion is detailing. As can be seen from the graph (above), 78 per cent of total promotional spending was focused on rep calls (including samples) to GPs and specialist practitioners (SPs).

There are significant differences in the way pharma companies approach marketing. In general, ethical companies spend a bigger share of their budgets on GP and SP meetings. As can be seen from the graph below, KRKA is much more focused on promotion to GPs than other companies. MSD spends more than one third of its promotional budget on meetings. Novartis is the only company with significant investments in clinical and post-marketing studies. Servier’s promotional budget is divided into three almost equal parts – meetings, promotion to specialists and promotion to GPs.

Interestingly, it is the quality not the volume of promotional activity and the ethical value of the pharma company that are proven to deliver more value in terms of clinician perception. For example, despite the fact that Servier is not the biggest promoter

**Objective & Ethical Behaviour (% of Ranked 1st)**

<table>
<thead>
<tr>
<th>Company</th>
<th>Objective &amp; Ethical Behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Servier</td>
<td>9.7%</td>
</tr>
<tr>
<td>Novartis</td>
<td>6.8%</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>6.6%</td>
</tr>
<tr>
<td>Menarini</td>
<td>6.4%</td>
</tr>
<tr>
<td>Gedeon Richter</td>
<td>6.2%</td>
</tr>
<tr>
<td>Pfizer</td>
<td>5.6%</td>
</tr>
<tr>
<td>KRKA</td>
<td>5.6%</td>
</tr>
<tr>
<td>Sanofi</td>
<td>5.4%</td>
</tr>
<tr>
<td>Astellas</td>
<td>4.2%</td>
</tr>
<tr>
<td>Abbott</td>
<td>3.9%</td>
</tr>
</tbody>
</table>

Source: CSD Rep Quality Survey, March-April 2011

**Split of Promotional Spend**

<table>
<thead>
<tr>
<th>Company</th>
<th>GP/FP Detailing</th>
<th>Meetings</th>
<th>Other (clinical trials, mailing, print advertising, samples)</th>
<th>SP Detailing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>20%</td>
<td>49%</td>
<td>27%</td>
<td>3%</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>27%</td>
<td>40%</td>
<td>33%</td>
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</tr>
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<td>Berlin-Chemie</td>
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<td>48%</td>
<td>31%</td>
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<tr>
<td>Gedeon Richter</td>
<td>12%</td>
<td>51%</td>
<td>14%</td>
<td>3%</td>
</tr>
<tr>
<td>KRKA</td>
<td>56%</td>
<td>13%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>MSD</td>
<td>21%</td>
<td>49%</td>
<td>35%</td>
<td>19%</td>
</tr>
<tr>
<td>Novartis</td>
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<td>48%</td>
<td>21%</td>
<td>30%</td>
</tr>
<tr>
<td>Servier</td>
<td>30%</td>
<td>32%</td>
<td>29%</td>
<td>22%</td>
</tr>
</tbody>
</table>

Source: CSD-Promotion, MAT 2011 Q1, 13 specialties, 13 cities
Pharmaceutical Market Europe August 2011

Using the internet, just 7.5 per cent of physicians have access to the internet and use it either privately or professionally. eMarketing is nice to have and can be used for very narrow targets, but it is not a way to get coverage. However, it is likely that pharma companies will explore alternative ways to communicate with physicians as well as using medical reps and the only one which offers the coverage they need is direct mail.

Complex Health Service Structure

Restrictions on promotion under the new model present huge challenges for pharma companies looking to ensure new drugs are included on state programme lists. They also offer the chance to enter the market in different ways.

While it is important to get a new Rx drug on the reimbursement list at national level if possible, with each of the federal, regional and municipal funds operating in parallel, failure to get a drug on to the federal reimbursement list does not preclude a company from targeting regional decision makers. The federal protocol is a reference, it is not mandatory, which enables regional funds to make the shift from using reps to key account managers (KAMs) targeting are concerned. First, the importance of distributors: in the state segment specifically, distributors play a most important role, as they select the trademarks for the tenders (INN) that occur across the 82 regions. There are around 100 to 150 tenders per day financed by state budget or hospitals across Russia.

Second, given that only 30 per cent of drug costs are paid by the state, pharmacists have a massive influence on drug usage, and are able to provide a vast array of drugs without prescription. In some cases pharmacists will replace the doctor’s prescription with an alternative product, often at the request of a patient looking for a cheaper alternative. Companies need to ensure market access strategies embrace pharmacists alongside GPs and hospital consultants in order to maximise product opportunity.

It is also important to understand the impact of KOLs and thought leaders on the treatment patterns of doctors and their prescriptions. This includes both the formal impact of KOLs on procurement and treatment standards. Equally important, however, is the informal influence. A few prominent thought leaders strongly influence the choice of many followers.

In addition, it is important to identify doctors’ informal networks of influence – Communities of Practice (CoP). These groups pool ideas and can be instrumental in creating new professional practices.

Information resource – prescription data

One of the main problems pharma companies face in Russia is a total lack of the information that has been a core component of the pharma sales model in other countries for years. There is no prescription data and sales data is provided by three different companies with limited granularity, making it hard to draw the required insights.

“Restrictions on promotion under the new model present huge challenges for pharma companies looking to ensure new drugs are included on state programme lists”

Furthermore, there is no in-depth information about healthcare specialists, with only the number of positions available made public. In addition, it is unclear how many GPs or consultants have more than one position. Indeed, some 30 per cent of GPs may work in two places, but traditionally pharma companies have had no way of determining accurate clinician data. Given the scale of the health service in Russia, this lack of information has made it difficult to target activity effectively.

With the huge number of specialists operating across this vast territory, one of the main components of successful market access is information about the target audience on named level. The new ability to access information about physicians and pharmacists is transforming the way pharma companies address the market.

The pharma industry now has greater insight into local thought leaders and CoPs at both hospital and regional level; they are building strong relationships with KOLs, authorities and patients’ societies to establish influence within specific therapeutic areas. This information can also be combined with prescribing trends,
enabling pharma companies to embark upon far more effective, and targeted, market access activity. For example, quantitative indicators allow companies to rank experts by doctor’s coverage and size of communities of practice, the strength of influence on prescriptions and the potential for prescribing to new patients.

PHARMACEUTICAL ROLE

One of the key differences between Russia and the rest of Europe is its specific drug consumption behaviour: Russians tend to self-treat much more than other Europeans. Virtually any Rx drug can be bought in a Russian pharmacy without a doctor’s prescription. Today there are nearly 50,000 registered pharmaceutical units in Russia, ranging from kiosks and pharmacies ‘on wheels’ to pharmacies, pharmacy points, storehouse, pharmacy chains, chain points and offices of pharmacy chains.

The role of the pharmacist is being strengthened by the fact that Russian doctors do not give prescriptions as such, but simply write recommendations on a piece of paper. This gives the pharmacist a degree of influence over patient choice, even when buying Rx drugs. This practice applies to drugs that are not available on prescriptions and are not included in the reimbursement list.

This is specifically relevant for patients who do not suffer from serious illness and therefore do not get drugs through any reimbursement system. In some cases it allows pharmacists to replace a doctor’s prescription at the pharmacy – often as a result of a patient perceiving the drug to be too expensive, although this also occurs if the drug is not available.

The challenge for pharma companies is in understanding this behaviour. Unlike other countries, data pertaining to prescriptions issued by a physician are not collected, which means there is no information on drug sales in pharmacies that result from a doctor’s prescription. As a result, information about patient flow and doctor’s prescription level can only be obtained through interviewing doctors or gaining access to their diaries, both of which would require a significant investment in order to attain enough information, especially for large specialities such as GPs, paediatricians and gynaecologists.

Yet the pharmacist is obviously an important component of the market access strategy: companies need to gain valuable insight into these individuals. Information from consumer flow to the average bill, purchasing turnover and other indicators, enables pharma to evaluate the potential of each pharmacy.

MARKET ACCESS IN PRACTICE

In Russia there are 11 cities with populations of over one million, and two cities with populations of close to one million. Around 40 per cent of the 600,000 healthcare specialists, including physicians and pharmacists, are concentrated in these 13 cities, which represent primary targets for companies entering Russia.

Because of the huge number of specialists and huge territory, one of the main components of market access in Russia and key to the effective promotion of a product is information about the target audience on a named level. Taking cardiology as an example, the first target for this class of products is a cardiology specialist, followed by GPs. According to the Cegedim Strategic Data (CSD) Promotion study
PARETO ANALYSIS:
CATEGORY A - 30% GPs OBSERVE 61% PATIENTS WITH ARTERIAL HYPERTENSION

among GPs in 2010, the most promoted drug class is the cardiology group, with a share of about 48 per cent.

Using a simple calculation, if each of the almost 24,000 GPs in the 13 largest cities requires 12 calls per year, a pharma company will be making 280,188 annual calls. Even if one medical representative can make 1,600 calls per year, the company would require 175 representatives, which is not sustainable in this market. Nor is it required. Not every physician needs to be contacted about a cardiac drug, nor should all physicians receive visits with the same frequency.

“With named information on the target audience, efforts can be focused on the high potential groups, thereby reducing time and material costs”

According to the categorisation of GPs in these 13 major cities, the market can be split into three categories. About 30 per cent of physicians see 60 per cent of patients with arterial hypertension (AH) – these are ‘High potential – A category’ doctors. The second segment, ‘Category B’, covers 29 per cent of patients with AH, and the ‘Low potential’ segment brings only 10 per cent of relevant patients (see graph above).

With this insight, there is no need to visit all GPs, or to call with the same frequency, in particular, for cardiac drugs. With named information on the target audience, efforts can be focused on the high potential groups, thereby reducing time and material costs.

OCCUPORTUNITIES AND THREATS

The Russian market is vast, fast-growing and clearly offers massive opportunities for pharmaceutical companies. Presently, market access is focused at regional and local levels to enable pharma companies to target opportunities effectively across what is an incredibly fragmented market.

However, huge structural and funding changes are on the way. The Russian government’s planned changes to legislation will fundamentally change the way health services are delivered.

From the introduction of new price registration for Essential and Vital Drugs (EDL) last year, to the move towards greater standardisation in care pathways, changes are occurring at every level of health provision as the government attempts to reduce self-prescribing and provide greater access and choice to healthcare services for its citizens.

Impact is yet to come

For pharmaceutical companies, the new policy has so far made little impact on prescribing practices at regional and municipal levels. However, EDL pricing is now based on the lowest prices paid in European reference markets, effectively creating a price freeze. And the EDL will be the basis of the new health insurance system which will be piloted in 2012 and will change completely the way drugs are prescribed and reimbursed across Russia.

“Pharma companies across Russia are beginning to improve market access strategies and tap into new insight about KOLs and prescribing influence”

Facing the challenge of multiple, overlapping models for healthcare delivery – from distinct federal, regional and municipal reimbursement lists to the ability of pharmacists to provide virtually any drug without prescription – pharma companies across Russia are beginning to improve market access strategies and tap into new insight about KOLs and prescribing influence.

It is those pharma companies that can adapt to this fast-changing model and leverage new access to an unprecedented depth of health professional information that will be best placed to maximise the considerable opportunities available across this vast territory.

The Author

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