

Interview with Michael Crow, Vice President & Area Director, GSK Pharma CIS

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Tags: [GSK Pharma CIS](#)

GSK CEO Andrew Witty has said that GSK must move away from selling “white pills in Western markets” in order to offset widespread generic erosion. This means diversifying the company’s portfolio into novel areas and putting greater emphasis on emerging markets. How is the Russian affiliate contributing to the realization of this strategy?

One of GSK’s strategies is to grow a more diversified business both from a product and geographical perspective and that is exactly what we are doing in Russia and the CIS. Over the last 5 or so years we have been growing our sales faster than the market and we plan to sustain this into the future through the continued investment behind our core brands and through launching new medicines and vaccines.

Looking ahead the number of product launches we have over the next few years is without precedent in my 20 years with the company and will be a very exciting time indeed.

In addition to the launches of innovative products we are also launching products which we have either acquired or entered into partnership with. A couple of years ago, GSK acquired a major dermatology company called Stiefel which had zero sales in my region. We are now in the process of launching these products which will bring additional growth and bolster our overall dermatology portfolio which is also very synergistic.

One very interesting partnership we recently entered specifically in Russia CIS is with CSL Behring — a top-ten biotech company — to sell their portfolio of plasma protein therapeutics. Their portfolio fits perfectly with GSK's and matches well our portfolio of high tech products and our local capabilities.

And last year we acquired in Russia a range of human recombinant insulins together with a new pen device to supplement our offering in diabetes.

So as you can see we are diversifying our portfolio to fit local needs.

But its important to remember that the core of our business today and for the foreseeable future is our innovative and classic pharma medicines together with our broad range of vaccines.

So would you say that your growth is mainly due to global company developments, or are there particular, unique strengths at this affiliate?

It is a combination of both. We are in the fortunate position of having globally one of the strongest pipelines in the industry but this alone is not a guarantee of success. It requires excellence in the local execution of our scientific and commercial plans with a continuous focus on ensuring everything that we do is done to the highest ethical standards.

GSK is the 6th-ranked pharmaceutical company on the global market. What is your understanding of the company's positioning in this region?

We're probably ranked about 8th on the Russian market when our vaccines business is included together with sales from ViiV (the Pfizer GSK joint venture HIV speciality company), - most market audits do not automatically include these since the sales are not recorded in the regular pharmacy or wholesaler surveys. Whilst ranking is important what is more important to me is our growth rate versus the market, in particular our volume growth rate. We are on a journey to establish our business in Russia and in doing so help modernize healthcare. This is not a quick process.

What are your leading business drivers?

We have growth coming from multiple areas thanks to having a reasonably balanced portfolio. From our broad range of vaccines to our innovative patent protected medicines to our well established patent expired classic bands to branded generics - all drive our growth. As a leader in respiratory, this is a significant part of our business with Seretide as the current flagship brand. This year, despite facing a generic challenge we still expect to grow volume. Just as Ventolin globally faced generic salbutamol 30 or 40 years ago yet still grows every year, so we expect the

same from Seretide in Russia today – and Ventolin! Why are we confident – when you put this into a patient perspective we estimate today that out of 1.5 million registered asthma sufferers only approximately 300,000 receive a modern combination product. COPD represents an even bigger opportunity with anything from 2.5 to 10 million sufferers but less than 100,000 patients receiving an optimal treatment. So as you can see the opportunity and patient need in respiratory is huge.

Another area that is increasingly more significant is our range of innovative oncologicals which has expanded in the last 2 years through new launches and indications and will continue to expand.

And then there is our range of classic brands, such as Augmentin, Paxil and Lamictal, all of which are growing very strongly in the retail segment.

How can GSK reach the remainder of these patients? Is it a matter of having to wait until the authorities expand reimbursement efforts?

In Russia there are several drug access programs, Federal, Regional and Institutional, making the market very fragmented. For a pharma company to truly succeed in Russia you need an organization that is capable of operating across the regions, from Vladivostok to Kaliningrad.

In GSK we have built a regional organization, dividing the country into six geographically separate businesses with regional heads that act quite like country managers. Rather than try to run everything from Moscow, our regional directors are empowered to run their businesses. This enables us to be more responsive to the needs and opportunities in the regions.

You have 6 drugs on the List of 57 Strategic Medicines to be Manufactured in Russia—a significant number. What does inclusion on this list entail for the future of these drugs? What options is the company exploring?

Of the 6 GSK products included on this list, several are antiretrovirals which fall under the remit of ViiV. The only product that is of significance to GSK Pharma is IPV vaccine which is why we are developing a partnership with a Russian biologicals producer called Binnopharm.

Why was it important for GSK to commit to this collaboration—is it simply to be in line with government objectives, or is there real added value for the company?

I think it is important, in a market like Russia, to align your business strategy with the government's objectives although this needs to be done in an economically efficient manner.

The supply of vaccines to the National Immunization Calendar has always been very specific, even before Pharma 2020, in that they had to be locally manufactured. This is because the Russian state

has always considered supply to the vaccination calendar as national security so they can be confident of continuity of supply and quality.

We took the decision 13 years ago to invest in manufacturing in Russia, with the creation of SB Biomed, a vaccines manufacturing facility located just outside Moscow. We localized the manufacture of Engerix B (Hepatitis B vaccine) at that facility, and Hepatitis B entered the national vaccination calendar shortly afterwards.

The reason why we chose now to collaborate rather than continue with SB Biomed is primarily due to speed and economics. Binnopharm has the infrastructure but lacks portfolio whereas GSK has the portfolio but lacks the infrastructure to localize more vaccines. Through partnering we are able to localize our innovative vaccines quicker and without the capital outlay of developing further manufacturing facilities.

Your partnership with Binnopharm is so far limited to packaging. What is GSK's assessment of the readiness of domestic companies to engage in high-level ventures? Could there be a deepening of this partnership, as well as further partnerships, on the horizon?

Partnerships involving sterile biologicals rarely involve the early phases of manufacture at the onset. Manufacturing stages are transferred in gradually as the partner gains the technical know-how. As part of our agreement with Binnopharm we are providing them with the technical support to upgrade their quality systems to international standards.

Your competitors are quickly taking more advanced steps. AstraZeneca, for example, has announced investment into a local R&D center in St. Petersburg. Is partnering in local drug production and transferring technology enough to maintain an edge in Russia?

Whilst pouring concrete makes headlines, it doesn't automatically translate into new products. GSK has long been involved in clinical research in Russia because of the quality of physicians in this country and because we believe in collaborating with leading clinicians, linking them globally with their counterparts in other countries to work on developing new medicines and treatments.

The way we see it, we will work globally with the best institutions and laboratories to bring new products to patients just as effectively and efficiently as is possible. If those laboratories and scientists are in Russia, we will collaborate with them.

Let's delve a bit deeper into your clinical trials program. You have more than 90 ongoing clinical trials in Russia, clearly preempting the clause in the Law on Circulation of Medicines that now requires local clinical research. How does Russia factor into your global clinical trials effort, and

why commit to such a large-scale program here?

Again, within the R&D organization of GSK, our main drive is to bring innovative medicines and vaccines to market as soon as possible. We have found, in working with Russian centers and Russian physicians, that the quality of data and the speed of delivery is outstanding. There are excellent physicians in this country, and excellent institutions to work with.

On the subject of legislation, Russia is taking steps toward a universal reimbursement system in healthcare. Do you believe this kind of system is feasible in Russia, and how would the prospective shift affect your business?

It is well publicized that Russia is facing a demographic crisis. This country has tremendous economic potential because of its natural and intellectual resources but with a declining population and high morbidity rates long term economic prosperity is severely threatened. In recognition of this threat the government developed the Health 2020 strategy with clear targets for improving life expectancy and decreasing infant mortality rates. Unless bigger steps are taken to improve the current healthcare system, these targets will not be met. How the delivery of better healthcare will be delivered is complex given the legislative structure of the Russian Federation. That said, the introduction of some form of a wider state subsidized drug access scheme must be a key part of the solution along with effective diagnostic procedures and patient management paradigms.

For GSK we have to be ready for these changes by ensuring our products are registered, that their efficacy is known and understood and that we have the right evidence to support usage.

Is GSK in place for whatever may come?

This is a continuous process as our product portfolio evolves. Fortunately and through good insight, we have long been working with leading physicians on the development of local data as part of our global R&D programs. Depending on the economic hurdles we may need to do more.

I doubt however the Russian market or our business will change overnight. Today over 55% of the Russian market is driven by patients buying medicines privately. With the introduction of wider drug reimbursement programs the market is unlikely to immediately switch to resemble something like the UK, Germany or France where the market is predominantly state pay. I suspect the government will initially focus on chronic diseases and conditions affecting mother and child. Oral antibiotics, and acute treatments, are likely to remain in the out-of-pocket segment for the foreseeable future.

We began to speak about the significant demographic problems in Russia. To fill in current healthcare gaps, companies operating in Russia must be proactive corporate citizens. As you said in a 2009 interview with Good2Work, “the interest of the company has to be always aligned with the interest of the patient.” Beyond drug marketing, how is GSK committing its significant resources to improve the health of Russian patients?

To me, this is at the heart of what we do - we share our knowledge, information, and experience to help doctors treat their patients better and to help patients better understand and manage their condition. From physician education programs, to engaging with patient groups—this is where we make our biggest contribution. Recognising the importance of these initiatives we take great care to ensure that all the information provided is evidenced and balanced.

Where would you like to be within the next five years, and what are the comparative advantages that will get you there?

I would like to see GSK even more deeply embedded into the Russian medical and scientific society; even more part of the fabric than we are today.

In terms of comparative advantages, I would cite the science that we have behind our products, applied in a Russian setting and the people we have in our organization as the key differentiators.

From a broader, industry point of view, I would like to see the dialogue between industry and state far more evolved. Currently, there is room for improvement from both sides. Too much time and resource is wasted today which could be better used working on improving healthcare.

Prior to the interview, we discussed your interest in running marathons. How would you compare running a marathon with running a pharmaceutical company?

Nice question! Firstly just as you usually don't decide overnight to run a marathon the next day you shouldn't decide to set up a pharmaceutical company in Russia overnight and expect immediate results - it takes preparation and discipline in the execution.

At the outset I think you need to know why you want to run a marathon and then define your objectives - is it a particular position or time or something else. Whatever the reason, it has to be challenging.

I then visualize what it is going to feel like at the end when I have succeeded - this is what keeps me going when it gets tough.

Once the objectives are set I then plan out my journey and define the milestones. I set myself a time for every mile – this is my clock speed.

If I fall behind in any mile I know I need to speed up to make sure I reach my goal.

It's the same in building a business in Russia – we set long term goals, develop a plan, define milestones and then measure performance against those milestones as the plan is executed, making adjustments along the way to ensure we stay on target.

Over confidence in the early stages can be very dangerous – at the start of a marathon for the first few miles you may feel good but you need to manage carefully the rate at which use your resources. Start slow, finish strong is something I always keep in mind. There is no easy way of running a good marathon. I think it is the same when it comes to building a good pharmaceutical business in Russia. You simply must put the time and effort in.

What is your final message to the readers of Pharmaceutical Executive?

The weather is awful, the bureaucracy drives you mad and Moscow traffic is a nightmare but I can't think of a more interesting and challenging part of the world to work in where you can make such a difference in society and do well in business.

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