Interview with Michael Sean Reilly, General Manager for Pharmaceuticals, GlaxoSmithKline Colombia

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Michael Sean Reilly: General Manager for Pharmaceuticals

Juan Carlos Berbessi: Medical Director

Maria del Pilar Rubio: Medical Manager for Vaccines

Gustavo Zapata: Finance Director

Juan Pablo Restrepo: Legal Affairs Manager

What is the strategic role and importance of Colombia within the larger global framework of GlaxoSmithKline (GSK)?

Michael Sean Reilly: Colombia is now considered a growth market that is part of GSK's region of Emerging Markets, which is currently subject to special attention by GSK. In Latin America there is a mix between stable, volatile, long, medium and short term high-profit markets. Colombia is one of the more stable markets and is not expected to grow excessively over the next few years. However, we expect to get a relative 5-10% growth without any high risk. We are a strong, reliable "brick" in terms of being able to count on us to get good results. The risk analysis for Colombia is normally a lot less than what you would see for other Latin American markets where you see frequent shifts in the market, the economy and the political environment.

Colombia is flat at the moment in the trade market with growth coming from the institutional market. The trade market is relatively stable with a tendency to decrease in value, as it did last year by 9%, with units holding stable. The institutional market has had compound growth of around 32% over

the last five years and there are projections for at least 16% compound growth over the next three to five years. The focus now is indeed on the institutional market.

In 2008 GSK corporate established several strategic priorities to drive the company into the next decade focused on: grow a diversified business; deliver more products of value; simplify the operating model. Which one of these strategies does Colombia best fit into?

Reilly: We are focusing on all of them. However, we are giving more weight to the strategic priority of “grow a diversified business.” What we are essentially doing is basically diversifying the portfolio. GSK before was very oriented towards internal intellectual property (IP) products. At the moment, however, we are looking for local growth opportunities from in-licensing products from European, Asian, or North American companies that do not exist here in Colombia; local growth opportunities from vaccines; and local growth opportunities from alliances with companies from China and India. We are looking to get into the branded generics business and we are in contact with companies from India to achieve that goal.

What are the specific product lines that are diversifying the portfolio and will be driving growth in the future?

Reilly: Our main focus for internal products is on oncology and vaccines. Those are our main growth areas for the future.

Juan Carlos Berbessi: We are also shifting into biotechnology. We are moving from the blockbuster strategy to a strategy that focuses on small molecules with specific targets that will create twenty five R&D lines instead of five lines as was the case in the past. We are also diversifying the portfolio so as to get opportunities in neglected diseases. Right now we are engaged in alliances that will get us the best-science and gold-standard products and not only on blockbuster products that we can market for only a few years of its patent life.

Reilly: Basically the strategy is not to put all the eggs in one basket. Instead of having one or two blockbuster products the goal is to have many medium-sized products in different areas. We cannot rely on blockbusters especially in Latin America. What we have are niche products from a corporate point of view. Locally we have to adapt to the market. That means that we, as a local company, can look for international licenses. We can look for partnerships with companies that do not exist in Colombia which is a new strategy and a new possibility for us.

How would you describe the state of biotechnology in Colombia today?

Reilly: The market is only developing at the moment. The biggest products we have are vaccines. We as GSK have very few other biotech products on the market at the moment. There are a lot in the pipeline, but few presently in the market. How do we see Colombia? We see Colombia developing in that area, with a robust legislation for biosimiliars in order to avoid poor copies.

Berbessi: GSK currently is in the process of establishing alliances with biotech groups who are investing in new molecules. Presently we have twenty-five to thirty alliances with small biotechnology companies. When these companies launch a new molecule we will initiate the process to get the approvals, undergo the clinical trials, and petition for GSK to own the patent and the molecule. We have the diseases here, we have the opportunity to commercialize their treatments, and we have patients who would benefit from these new opportunities.

GSK global is going through a corporate restructuring program and the goal by 2012 is to save about £500 million which will be spread equally between R&D and administrative costs. What is the expected trickle-down effect of this for GSK Colombia?

Reilly: We are growing. Our headcount is on the increase because we adapted shortly after the merger. We have gone through various phases of restructuring since 2002. At the moment the structure we have is in line with market needs and now we are in fact adding on extra specialized field force to manage Oncology. With the purchase of Stiefel we are taking in and increasing our sales force also. Although we constantly reassess the adequacy of our headcount as compared to our growth target and market benchmarking, needs and conditions, currently countries in emerging markets where growth potential is seen, such as Colombia, are investing.

While you referenced earlier Colombia to be a stable, reliable "brick," with its steady growth potential do you foresee it joining the elite class of acronym-ed BRICs?

Reilly: No, it does not have the population for that. When you look at the BRICs the population of those countries is what makes them the BRICs. Colombia is the third business market in Latin America and in pharmaceuticals we are now the fourth. I would not consider Colombia to be a BRIC and I think it is a very remote possibility. But that does not discount its credentials as a stable market, a good investment market, and a market in which if you work well you can be successful with a lot less volatility towards the future. The Colombian economy is very well run. The Bank of the Republic has managed policy very well. We have had negative growth in GDP only twice in the last eighty years. When you look at Latin America Colombia is probably the most stable economy.

How is the current Social Emergency Crisis and its emphasis on cost-competitive products affecting the innovators of research-intensive and, therefore costly, medicines such as GSK?

Reilly: I think that what you said is correct – there is a focus on cost-effectiveness. We consider that the system in Colombia is going through a financial problem. One of the reasons is because the actual Obligatory Health Plan (POS) has not been updated on a regular basis with new technologies in the way new technologies should be included based on health economic studies. We see and expect the government in the future to get the recently established Comisión de Regulación en Salud (CRES) to have a validated process on competitive health economic studies

and based on that we can include our products within the PO. We understand that the Colombian government is working with various international agencies to see how this actually works in practice in other countries. We expect the same to happen here. Obviously there will be price restrictions and we are fully compliant with the restrictions that the government has set at the moment.

We understand that the government is not a protectionist government. The Colombian government agrees with a free market trade and that they will always try to encourage free market trade.

Berbessi: We are facing an evolution of the system. GSK is working alongside the government to provide them with information about the cost-effectiveness of our products so that they understand that while our products carry a cost, they come with an equal medicinal value. The goal is to inform physicians of the most efficient ways to invest the money that the government has given them for healthcare. Without this data, the negotiation amongst institutions will only focus on price as a quantifiable number. We are providing data so that the discussion does not become just about money. Our Sales Representatives are specialized on this data, so they can convey it to stakeholders in the POS system; stakeholder being not just practitioners and prescribers, but also government administrators so that the entire panorama of the discussion centers on a pharma-economic environment.

Reilly: One of Andrew Witty's strategies is to give more access to more patients. In emerging markets we have to look for access. In certain products we are reducing prices in order to increase the number of patients who can be benefited by our products. That is in line with what the government is looking for: competitive pricing and more access for patients.

The Social Emergency has engendered healthy discourse and dialogue about possible resolutions to fix the system. A stance that is strongly advocated by the local laboratories is for a shortening of patent enforcement in order to maximize patients' access to affordable drugs. Is this more of a threat or an infeasibility from a multinational perspective?

Reilly: The patent elimination discussion has been going on for many, many years and will continue for many years. The national companies have launched repeated attacks on patents and data protection. The industry would expect that the patents laws be maintained. 98% of the WHO list of essential medicines is off-patent and when you look at the overall number of patents in Colombia it is minimal.

Juan Pablo Restrepo: The topic of patents and IP protection has become more of a political speech. Colombia has executed multiple international treaties and is currently negotiating a couple of free trade agreements that oblige the country to guard and protect IP rights such as patents. Even though there is a strong push by different sectors in Colombia to eliminate patent and data protection of medicines, I truly believe that pursuant to the aforesaid international legal obligations of Colombia, the country cannot take the decision from one day to another, to eliminate patent and

data protection standards. For instance, in a free trade agreement with the US or Europe, the country would not be able to comply with their strict patent and data protection laws, if the country would decide to amend the current IP protection regulation. Bearing in mind the importance of complying with international treaties and the need to enhance foreign investment, I do not see there being any significant changes to patent and data protection laws in the short-term.

Reilly: We as a MNC would be worried if patent protection would not be given in the future. The future of the pharmaceutical industry in general is based on innovation and new technologies.

Berbessi: Also, new products will be more expensive if we consider a shift into the biotechnology sector. For the chemical synthesis – the product that we are using and consuming right now – there are too many controls; but for bioproducts we are going to be more accurate. We will use different cells and different cultures. We need to ensure that we are using the same technique in order to provide the same product in one of the batches that we are launching in the market. That is why we need to protect the innovation.

Is Colombia involved in GSK's Open Innovation Strategy that Mr. Witty announced last month?

Reilly: We in Colombia are solely focused on importation and commercialization, except for Clinical Trials in vaccines.

Maria del Pilar Rubio: GSK has been active in clinical trials in Colombia since 1997 taking into account the epidemiological profile of Colombia and the importance of the vaccines in the Public health of the countries. One example is the successful vaccine against Rotavirus, whose clinical trial has 4,000 participants in Colombia and is included in Colombia's universal mass vaccination program. We are also starting the pneumococcal Phase II schedule vaccine which we trust will be included in the mass vaccination program in the next future. The importance of these clinical trials in Colombia is not just the fact that we are conducting them, but also that the physicians and health professionals who are participating in these studies are having access to the latest on medical and scientific research and upgraded infrastructure.

What are some of the similarities you see between Irish, British, and Colombian culture and how do they blend together in the corporate culture?

Reilly: Colombia is going through a lot of the problems that Ireland has already seen such as terrorism and migration and thankfully both have improved considerably in recent years. Although we are a British company we have to adapt to local traditions, cultures, and ways of working.

Berbessi: The culture of GSK worldwide is centred on four main values: Integrity, Focus on Patients, Transparency and respect for People. These are four principles that every person in GSK needs to know. The application of these values on a day-to-day basis depends on the interaction

with local customs and cultures. But for me, integrity is the core principle.

Restrepo: I am also a US citizen and have worked before in American companies. The big difference with GSK is that it is a very conservative company. As a lawyer, it is an ideal world to work in because that conservatism and integrity is present in all of our decisions and ways of working. Our boldness and conservative culture, which come from the global reach of GSK and the need to have a unified corporate culture based on common strategies and values, , gives us the certainty that we are doing the right thing at the right time and with the right people. The conservative and ethical culture implanted in our DNA by our General Manager has proven to be very successful in a Latin American environment.

Gustavo Zapata: The key for me is integrity. Being the financial director in Colombia you have to ensure that the corporate guidelines are aligned with local laws and regulations. We have to balance both systems and comply with all requirements. While we are a British company we have a bit of an American influence in our internal controls. We are really a mix.

Integrity in a corporate culture touches upon Corporate Social Responsibility (CSR). Is GSK held to a higher standard in CSR being the one of the top two pharmaceutical companies in the world?

Reilly: I think there are two ways to look at CSR: internal and external. Internally is about how we treat our employees. From that regard the people who work here are very well respected. We try to make the work environment as pleasant as possible and as much as I can say, I believe the people who work here are happy.

Restrepo: For instance, several years ago in Colombia the government issued a new law on labour harassment. Many companies had to amend their internal controls to adapt to the new standards that were set. GSK did not have to make a single amendment to any of its internal policies because its corporate laws were already stricter than the new laws that were passed.

Reilly: With society and the community we are always in full compliance. It comes from the culture of integrity. We are always trying to be in the forefront.

Zapata: I am proud to work with this company because here an employee can map out opportunities for professional development and a prosperous career. Because of that, GSK Colombia is now exporting people to many countries. In the BRIC countries we have two Colombian general managers (GM); a Colombian GM in Brazil and a Colombian GM in Russia, and many Colombians hold regional positions in Latin America.

Reilly: The work ethic in Colombia and the level of professionalism here, you will not see in many other countries. The people here try harder. Additionally, the level of education here is superior to many other countries in Latin America. Because of all this, Colombia is seen by other Latin

American bosses as a talent pool.

What advice would you give to a foreign CEO coming to work in Colombia?

Reilly: First and foremost, get a good team. Second, there are a lot of good opportunities in Colombia. If you want to do things right you can be very successful here. Third, don't expect to have a windfall overnight. It is a market that grows slowly but is a lower risk than many of our neighbouring markets. People are now starting to see Colombia as an investment market, which is another comparison with Ireland. Until Ireland resolved its political issues, no investment came. Over the last six years Colombia has experienced a very similar situation. The security situation has improved enough to attract foreign investment as well as lure Colombian investors who have their money abroad to start bringing their money back into the country.

What would be your final message to the readers of Pharmaceutical Executive about the potential of Colombia and the work of GSK here?

Reilly: I think Colombia is a market you have to be in. It is a progressive, stable market that is growing. As the security situation improves so too, will the economical situation. We, as a company, are looking for opportunities with companies that do not have presence here. It is not only the national companies who are trying to forge alliances; we are the first in that search for alliances. Companies who do not want to come in directly can come through us.

Berbessi: We are searching for alliances as a way to provide new science. We are very interested and focused on patients' needs. To complete this promise we need the best alliances in the market that who offer high quality products.

Reilly: Colombia is riding a double wave. It is riding the Emerging Markets wave where in general things are improving and it is also riding the wave of improved domestic security. When Colombia rebounds the return will be better than in any other market.

Zapata: I think Colombia is a country of opportunities. We participated in a meeting with Minister Plata and he mentioned that Colombia is preparing for eight big, new projects to remake the products that we have. A huge growth opportunity for Colombia is medical tourism of people from abroad coming here for surgical procedures. If more people come they will need new medicines and new molecules. We will be aligned with these opportunities especially because the government has decided to support the growth of this sector.

Rubio: I am Colombian and I feel so proud to work with GSK. My area is vaccines and I think it is wonderful that so many Colombian children are using GSK vaccines to improve their quality of life. We feel very proud that they are using our vaccines to lead healthy lives. The economic growth of the country is a tremendous boost to the development of national health programs.

Restrepo: Similar to what my colleagues have stated, the calibre of professionals here is extremely high. People are extremely good at what they are doing. Also, while many companies constantly preach about integrity and anti-corruption, it is amazing how seriously GSK goes in practicing those virtues. For Instance, there is a worldwide team appointed exclusively to carry out anti-corruption initiatives. We are constantly undergoing trainings in order to fully comply with applicable laws such the US Foreign Corrupt Practices Act (FCPA), US Sarbanes-Oxley Act and the UK Anti-Bribery legislation. GSK Colombia is conservative from a legal perspective and we are always one step ahead of what the government establishes for compliance. Finally, regarding the two waves that Sean mentioned, I believe that from a geographical perspective, Colombia's business friendly model has proven to be more successful than neighboring country's models and thus I believe that a third wave will flood Colombia with foreign investment from companies that will prefer to invest in a political and economical stable country rather than in a volatile one.

Reilly: Colombia is the best kept secret in Latin America. I have been here for twenty years and have no intention of leaving the country. It is a wonderful country with excellent people and you can live a very good life here – despite what Hollywood shows. Colombia is a very resilient country that has gone through bad times which has toughened their resolve and strengthened their resilience. People will come back just like they did in Ireland. The investment from foreign and local companies has increased substantially in Colombia over the last 6 years. People now believe again in their country and are very determined to make it successful. Come and see for yourself.

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