#### Interview: Alexandre Williams – Managing Director, Athena, India

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Alexandre Williams, founder and managing director of Athena, an international company with an Indian manufacturing basis specialized in life cycle products, provides insights into some key trends shaping India's pharmaceutical industry and exports. He also documents Athena's plan to launch over 50 new products in both advanced and strategic emerging markets in the coming years and highlights how the company has been targeting both specialty pharma companies and pure generics players interested in differentiated, branded generics.



India based manufacturers have been very successful on the international stage over the past fifteen years, by notably leveraging the country's competitive manufacturing cost advantage. Leveraging on your experience, what have been some other key success factors that our readers might not know?

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A first aspect that should not be overlooked relates to the fact that India is primarily an English-speaking country. As basic as it might seem, this specificity has emerged as a strategic asset – especially vis-a-vis other ambitious emerging countries such as China – when it comes to assembling compliant, complex registration dossiers aimed to international regulators.

In the meantime, the fierce competition and complexity of the Indian market have undoubtedly propelled the export capacity of Indian companies. Firstly, as the Indian market is extremely price sensitive, Indian companies have become experts in mastering their end-to-end cost-effectiveness, thereby sharpening their competitive advantage in overseas markets. Secondly, the Indian market's low margins have prompted Indian companies to rapidly enter more attractive and prospective international markets to increase their profitability.

Furthermore, I would also highlight that a tremendous number of pharmacy students graduate from India's universities every year. This provides domestic companies with a well educated, easy-to-recruit workforce, while the pharmaceutical sector benefits from a great reputation in the country, which drains a lot of talent to the industry.

# Nevertheless, according to Pharmexcil data, India's formulation exports decreased by 0.47 percent in FY 2016-17. Do you see Indian pharmaceutical exports renewing with their historical growth rates in the coming years– or domestic manufacturers are truly at a turning point?

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I believe that it was just an exceptionally bad year for Indian exports and that the latter will continue to grow moving forward. In this regard, I expect that export growth in the US will pick up again – especially considering that over 60 percent of the demand is driven by chronic disease, and the latter will not vanish overnight. In the meantime, Indian companies have been increasing their efforts to develop stronger footprints in strategic emerging countries such as Brazil, Russia and some African and Asian countries – a strategy which should bear fruit soon.

On the other hand, I expect that Indian companies will continue suffering from increasing scrutiny pressure in the coming years, leading them to significantly step up their investments related to quality and regulatory controls. In the meantime, some variable costs, such as electricity supply, are much more expensive in India than in Europe. Taken all together, these factors will accelerate the weakening of India's manufacturing cost advantage, which is already affected by Indian workers' expectations to see their wages being increased by 10 percent a year – regardless of the inflation rate. As a matter of fact, India has already lost its manufacturing cost advantage vis-à-vis several European countries – especially above a certain volume of goods – as exporting from India moreover implies bearing higher logistic and tariff costs.

Although many Indian executives do not want to admit it, this evolution is ineluctable, and India will undoubtedly go down the same road as China, where the minimum salary today revolves around USD500 a month, which is higher than in some Eastern European and CIS countries.

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Looking forward, I however expect that more and more R&D activities will be conducted in India, as the cost/quality profile of the country keeps on improving and will not be equaled anytime soon.

#### Although Indian companies used to dominate the global API industry, over 85 percent of all raw materials used in India are now imported from China. Do you see this overdependence on imported APIs as a serious threat to the competitiveness of India's manufacturers?

After having taken over the global market thanks to their unbeatable prices, Chinese APIs manufacturers have indeed been leveraging their monopole positions to increase their

prices at a sustained pace. In the meantime, it is true that Chinese producers today have to cope with heightened environmental regulations, which negatively affects their cost structure and motivates them to drive their prices up. However, the rising prices of Chinese APIs will affect their global competitiveness and render possible – again – for Indian companies to compete against Chinese API manufacturers.

In the meantime, Indians are particularly patriotic, which could incite stakeholders to reduce the country's dependence on imported raw materials. Furthermore, to the contrary of many countries, India's API and chemical industries haven't been dismantled, and they are then ready to experience a new boost.

Only time will tell if the required resources will be injected to India's APIs industry or if industry's stakeholders will exclusively concentrate their efforts on higher added-value projects. However, I personally expect India's APIs industry to rebound in the future and regain market shares in the Indian and international markets alike.

## Could you tell us more about yourself and how you set up Athena in 2011, an international company with an Indian manufacturing basis dedicated to innovation in drug delivery systems?

Eager to discover the world, I joined in my mid-twenties France's Ethypharm, which was at that time a B2B company specialized in drug delivery systems. I therefore worked in several emerging countries, including China and India between 2001 and 2006, two markets where I had the mission to turn around the affiliates' performances. In 2006, I was promoted as Ethypharm's VP Head of Business, before a private equity firm entered Ethypharm's capital. The latter however wanted to shift the company's focus from B2B to B2C and divest some assets, including the Indian operations. I seized this opportunity, and this how Athena Drug Delivery System was actually born.

Our beginnings were not easy, as we had to build a new, standalone company, which implied developing and registering a new product portfolio in a variety of markets. In line with the rapidly increasing regulatory pressure affecting formulation manufacturers, we also had to conduct significant investments in our Indian plant over the past years.

We however recently started to experience an eye-catching momentum in terms of product launches, after having complied with lengthily registration timelines for over 35 products in 20+ countries. Furthermore, we plan to launch in both mature and emerging markets more than 50 products in the coming years, which will lead us to double or triple the production capacity of our Indian plant. Leveraging the recent registration of these products, we expect to double our current sales of USD seven million within the next twelve months.

### Who are your main customers and which industry trend has been driving the demand for Athena's differentiated, branded generics?

To better understand the demand for Athena's products and services, we first have to take a step back. While generics companies had the wind in their sales for several decades, the latter have faced headwinds in the past years, mostly because of the low number of innovators going off patent and rapid price erosion in existing products. In a context of drying pipeline for generics companies, the latter have been gradually expanding their scope of action to OTC products, branded generics, and also mature, branded products. In this context, transactions between pure generics companies and specialty pharma multiplied, such as Mylan's acquisition of Abbott's non-U.S. developed markets specialty and branded generics business. This is exactly the kind of demand and customers that Athena DDS is targeting: companies looking for differentiated branded generics, i.e. a generics molecules with a life cycle that does not exist yet or that is still very rare on the global market. We then take care of the product development and manufacturing, while our partners handle these products' marketing in targeted markets.

Finally, in mature markets, we even saw specialty pharma companies transferring the promotion of their mature products to their generics arms, such as Novartis and Sandoz. As a result, our products can be promoted by specialty pharmaceutical companies or sold by purely generics companies, which want to develop a portfolio of differentiated, branded generics.

#### Which markets are you targeting in priority?

As our Indian plant is not FDA-approved, we are not yet present in the US and have been concentrating our efforts on Europe and Canada as well as on key emerging markets, which I am overseeing personally. Athena's core expertise is in life-cycle products – or differentiated branded generics, and leading pharmaemerging markets are as attractive as mature markets for this kind of products.

We have a solid strategy for emerging markets, and – despite our smaller size – we actually follow the same approach as some multinational companies. In this regard, we plan to enter Indonesia, where two of our products just got registered, and consolidate our presence in South Africa, whose regulator has already certified our manufacturing plant. We are also present in Algeria and Egypt, which are two key markets in the African continent, and we recently inked a contract with a Nigerian company, while we are currently negotiating with two other Nigeria-based companies.

Looking at the BRIC, one of our products just got registered in Russia and we expect to receive two more registrations in the country before the end of 2018. In Latin America, we are particularly focusing our efforts on Brazil and Mexico, as well as Colombia and Chile.

Nevertheless, some of the aforementioned countries have recently decided to boost the domestic production of locally consumed drugs. Although we will continue servicing some markets from our Indian hub, we are also looking at setting up a new manufacturing

capacity in a strategic country. As a matter of fact, we have already started transferring some manufacturing activities to France, where we work with CMOs. Overall, our main objective will be have an FDA-approved factory, which will allow us to enter the US market and leverage the experience I have honed in this country for years when I was at Ethypharm.

#### What will be your final message to our international readers?

Through Ethypharm and Athena DDS, I have been working on life cycle products for a long time, and I am ready to share this experience with companies aiming to build a portfolio of differentiated, branded generics.

In the grand scheme of things, the latter's game-changing potential should not be overlooked: life cycle products are highly needed products, which can bring great outcomes to patients. As per Athena, our overarching objective is to develop the best combination possible between a given molecule and a life cycle technology, to the benefits of our partners and patients around the world.