Interview: Bharat V. Daftary – Chairman & Managing Director, Bharat Serums & Vaccines (BSV), India



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Bharat V. Daftary, chairman and MD of Bharat Serums & Vaccines (BSV), a biopharmaceutical company with R&D units in USA, Germany & India and with a presence in over 76 countries, provides insights into the biotech landscape in India and its expectations for the fertility and women's health markets. He also highlights BSV's ambitions to develop two new biologicals in the critical care field and the company's enduring commitment to "

bring life to life*" through the development of differentiated, complex, and highly needed products.*

BSV has forged itself a strong reputation as a frontrunner among the Indian pharmaceutical industry. Could you share with us some key achievements and milestones reached by the company?

Founded in 1971 by my father, Bharat Serums and Vaccines initially focused on plasma fractionation. While we emerged as the first company in the country to operate in this area, our objective was to render India self-sufficient in plasma products. Nevertheless, when I took over the company in 1987, the soaring prominence of life-threatening infectious diseases and viruses like Hepatitis B, HIV and HCV turned the plasma business into a particularly volatile market: huge quantity of products were destroyed overnight by regulatory authorities, at a time where rapid test kits were not yet available to detect emerging subtypes of these diseases. As part of a diversification strategy, we started developing chemical entities, entering the equine immune globulin segment and the biotech field in general.

In this regard, one of our main aims was to ensure India becomes self-sufficient in equine immune

globulins, and we introduced to the domestic market a polyvalent snake venom antiserum, which is effective for all four venomous snakes responsible for most snake bites in India. The latter is a purified and concentrated preparation of serum globulins obtained by fractionating blood from healthy hyper-immunized horses, and BSV proudly stands as one of the largest manufacturers of this product in the world. We also became the only Indian manufacturer in the world to produce antithymocyte globulin *[which is obtained by processing hyper-immune serum of horses immunized with human thymocytes – Ed.]* indicated for the treatment of moderate to severe aplastic anemia in patients not suitable for bone marrow transplant. This product has been very well accepted by the Indian market as well as in several countries around the world.

Leveraging on our plasma expertise, we then decided to develop our own monoclonal antibody, Rhoclone, a sterile preparation of Monoclonal Human Anti-rhesus Immunoglobulin (lgG1) containing antibodies to Rho-D. While this product was initially launched in 1998, Bharat Serums is still the only company in the world that holds this product in its portfolio. A few years later, we also developed the world's first monoclonal antibody for human tetanus, a disease that used to cause a huge number of deaths in India because of the poor immunization coverage of the population. Both products are now marketed to many countries around the world.

Additionally, I want to highlight that BSV did not shy away from the biosimilar revolution that has been shaping the global industry over the past fifteen years. BSV entered the Biosimilar segment to offer a long term commitment to patients by offering next generation products based on recombinant derived proteins. In 2008, we launched Foligraf in India, India's first indigenously researched and developed rFSH biosimilar product, which was followed by a recombinant HCG biosimilar launched in March 2018.

On the chemical side, we also specialized ourselves in complex, difficult-to-make generics, while our portfolio mostly comprises injectable and intra-venous products – and this stands as a great differentiator vis-a-vis the rest of the domestic industry. In this regard, we became India's first company to produce generic versions of Goserelin depot and leuprolide depot. Again, both products have been very successful in India, and we export them to international markets too.

So far, very few Indian companies have been able to successfully develop biologicals, what has been your recipe for success in this regard?

Around ten years ago, we set up a biological API plant near Aachen, Germany, which handles the manufacturing of our biological products. Built as a greenfield project, this EMA- and FDA-approved facility allows us to directly export one of our products to the US and to other European countries. Thanks to this facility, we can rely on our own APIs while all other Indian companies import them from China. Overall, I believe that this front-end manufacturing unit based in a regulated market has truly propelled our ambitions and allowed us to gain the trust of prestigious customers: as a

matter of fact, we just entered into a new large-scale agreement with a prestigious Japanese company for the manufacturing of an urine-derived product.

In the meantime, most of BSV's biotech products target therapeutic areas and product categories with a limited number of competitors. While we expect to swiftly bring our highly purified human follicle stimulating hormone (hFSH) to European markets, we will then emerge as the third company after Ferring and IBSA to offer it in the continent.

What is your assessment of India's potential when it comes to developing biotech products?

Some Indian companies are producing remarkable biotech products, but bringing these products to regulated markets requires performing extremely expensive clinical trials, whose costs are unsustainable for most Indian companies. As a result, mid-size Indian biotech companies tend to primarily target developing and semi-regulated markets, where regulators recognize data from clinical trials performed in India. As per BSV, this implies we must consider teaming up with strong partners to conduct crucial trials for regulated markets.

Given these high development costs, one key success factors lies in the capacity to access external investments and founding. How would you gauge the Indian context in this regard?

If a given biotech company is doing well and financial institutions believe in its strategy, I believe such funding is available in India. I have personally favored a more self-reliant approach, where our own revenues nurture the development of new products.

I do not say that this approach is the best way forward for all Indian biotech companies, but it has truly brought interesting outcomes to our company. Bharat Serums and Vaccines was initially set up with a paid-up capital of USD10.000, which – when I took over in 1987 – still did not exceed USD10 million. In 2018, BSV stands a profitable company displaying top line results of over USD120 million, with 30 percent of our sales coming from international markets.

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Historically, gynecology has been BSV's main area of focus, and this TA makes up around 80 percent of the company's sales. How would you rate the growth prospects of this niche in India moving forward?

We believe that the women's health segment in India still offers tremendous opportunities, while it has been growing at a CAGR of 20 percent over the past years. In terms of new growth avenues, we noticed that some mature products are no longer available in the country though they are still highly needed, while there is also a growing demand for natural products, especially for well identified conditions that would not exclusively require chemical products.

An unsolved issue with urine-derived fertility injectable drugs relates to the fact that there is a

possibility of batch to batch variation due to the variability in the starting material. As a result, BSV decided to develop the world' first recombinant product in the fertility area, which would allow to eliminate variations as all products will originate from the same cell line. We are still enrolling patients for our Phase I clinical trials, which has been advancing at a very interesting pace. Leveraging recent technology advancements, I believe this first-of-its kind product could moreover be reasonably priced and consistent than urine-derived fertility products.

Vaccines also emerges as a promising field, and BSV is already teaming up with one of the world's largest manufacturers of vaccines for a product targeting women amongst other areas.

Last but not least, one should not overlook the fact that many diseases are still under diagnosed among the Indian population, therefore nurturing the demand for rapid diagnosis could enable physicians to perform comprehensive screenings within a few minutes.

Growing demand in the women's health segment has caught the attention of an every-increasing number of competitors. What will be the key success factors to outperform the competition?

A key aspect to consider relates to sales management, and we will put a special emphasis on continuously increasing the productivity of BSV's 300 sales reps active in the fertility arena. Although our company's headcount is smaller than those of some Indian heavyweights, BSV's revenues per person places our company as one of the top performing players in the Indian industry. This is due to the quality of our differentiated portfolio of complex products and to our efficient sales monitoring. Looking forward, one of my overarching objectives is to significantly strengthen the training of our sales reps and provide them with more science-based selling methods.

Overall, I must admit that our enduring commitment to the gynecology and critical care communities is already paying off, and physicians are eager to meet our sales reps. This exceptional trust has truly evolved into a win-win relationship; in this regard, I can give you a concrete example which concerns *enoxaparin*, a blood thinner marketed in India by 80+ companies, including Sanofi (the originator). As part of my frequent contacts with the Indian medical community, gynecologists highlighted to me that they could not access this product in India and this prompted BSV to develop it. I was extremely surprised, as over 80 different brands of this molecule do exist in India; however, none of these companies' representatives were apparently visiting gynecologists, while this product must be daily injected to mothers experiencing difficult pregnancies during 180 days!

We developed this product and rapidly gained the second largest market share in India for *enoxaparin* – after Sanofi. We then developed a new dosage form enabling self-injection through a multi-dose pen and became the first company in India to market such technology in this product

category. Although competitors swiftly started copying our pen, gynecologists have remained loyal to our *enoxaparin*, because they trust our company and its products.

Overall, our brilliant reputation with Indian gynecologists has allowed us to reach the third rank in this market category; leveraging on recent and upcoming product launches, we should shortly reach the second position.

In this regard, do you envision in-licensing partnerships to further enriching your portfolio?

We have already signed in-licensing partnerships with European and US companies, and these products will most likely reach the Indian market within the next three to five years. Rather than in-licensing products that are already available in the country, we concentrate our efforts on life-changing treatments that are not yet accessible to the Indian population. So far, we have only engaged in single-product partnerships, and we are also interested in engaging in broader partnerships with international partners aligned with our vision and eager to benefit from our expertise.

While most Indian companies have typically prioritized exports over their domestic market over the past decade, only 30 percent of BSV's sales come from international markets. How do you explain this difference?

As mentioned earlier, we have always preferred a self-reliant approach and funding our growth through internal accruals only. As a consequence, the pace at which we have expended our production capacity was slower than the rapidly increasing demand for our products, especially for biologicals. We are now waiting for our Indian biotech plant to be EU-approved, which should help us to propel the growth of our exports. As a matter of fact, the latter have been increasing at an annual rate of around 30 percent over the past three years.

In the meantime, one should not overlook that India already stands as a large market to service, while it is moreover growing at a very interesting pace. However, pricing power remains a problem, and this is particularly true for BSV's complex products, which typically come at higher prices than basic treatments. Our products should nevertheless benefit from the recently announced National Health Protection Scheme, which aims to provide a health insurance cover of INR 500,000 [USD 7,800] for each family per annum and cover more than 100 million vulnerable families, especially in rural areas. We still need to see how and at which pace this ambitious scheme will be put into motion, but the Indian Government has so far proven itself extremely reliable when it comes to reform implementation.

In this regard, we also hope that the government will set up dedicated purchasing schemes for essential products, including for biologicals. For example, some areas of India are particularly affected by snakebites, but public hospitals do not have antidotes *[roughly 46,000 people die of*

snakebites in India every year, according to the American Society of Tropical Medicine and Hygiene, accounting for nearly half of the 100,000 annual snakebite deaths the world over – Ed].

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In line with BSV's heightened international ambitions, which markets will you focus on?

Currently, our main export markets are Philippines, Russia, and Ukraine. Our products are also available in some South and Central American countries such as Colombia and Venezuela, and in many African and Middle Eastern countries, including Algeria or Turkey.

Our focus moving forward will be on assembling stronger registration dossiers accepted by more stringent regulators, such as South Africa, Mexico, and Brazil. As a matter of fact, we are currently negotiating with a large American company – one of the top five biotech companies globally – to bring one of our biologicals to Brazil: this partner recently completed the due diligence process of our plant, and we hope to be inspected by ANVISA within the next twelve months.

While we will continue to develop our global footprint step by step, another way to bring our company to the next step will be through the in-house development of new biological entities targeted at unmet medical need for the Indian patients. In this regard, we just started the pre-clinical phase for two highly needed biologicals in the critical care arena. I am terribly excited about these two products, which could save a large number of lives and have a game-changing impact in ICUs all around the world.

What is the development pathway that you envision for these two new biologicals?

As per our development strategy, we will first look at bringing these products to India, before – eventually – looking for partners to launch them in international markets.

I believe that we can develop, manufacture and bring these products to India without relying on partnerships. In this regard, I am particularly confident in the skills and creativity of our California-based R&D center, where we develop all our cell lines before transferring them to and scaling up in India. I believe that our chances of success exceed 80 percent, while so far our failure rate for all complex products hasn't exceeded ten percent.

Bharat Serums' mission is "*to bring life to life*"; so our overarching objective is to ensure patients can come back home alive from the ICUs and enjoy healthier lives thanks to our products. At the end of the day, what matters to us is to save lives – regardless of the country of origin of the patient.

What should we expect from BSV within the next five years?

My only dream is to successfully bring differentiated products to the world and continue developing new treatments – and I believe that our sales will increase accordingly. In the grand scheme of things, the key success factor for Bharat Serums moving forward is to continue being different. Every pharma CEO has its own priorities, whether it relates to turning around his or her company,

going through a strategic M&A phase, expanding the company’s reach, or – as per Bharat Serums and Vaccines – striving to bring new products to the patients. Chances are that we might not succeed in this crucial endeavor, but at least we would stand proud for having tried to fulfill this noble vision.

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