

# Interview: Dharmesh Shah – Founder and CMD, BDR Pharma, India

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*Dharmesh Shah, managing director of BDR Pharmaceuticals, a company with a strong expertise in oncology, intensive care, and other therapeutic areas, provides us with an insightful overview of the main trends shaping India’s pharmaceutical industry, while documenting BDR’s eye-catching achievements and areas of expertise, as well as the strategic alliances that the company is looking to establish in the US and Europe.*

**India-based manufacturers have been very successful on the international stage over the past 15 years, notably thanks to India’s competitive manufacturing cost advantage. Leveraging your long-standing industry experience, what have been some other key success factors that our readers might not know?**

When considering the rapid success of the Indian pharmaceutical industry overseas, another element that comes to my mind is our country’s vibrant entrepreneurial spirit combined with the great level of scientific knowledge it holds. In this regard, most Indian success stories have flourished as the result of these entrepreneurs’ hard work and bold strategies, while the domestic industry has historically developed itself despite the absence of dedicated government support, which has led Indian companies to focus on reverse chemistry rather than new chemical entities (NCE).

**Would you say that the Indian pharmaceutical industry is still in an ascending phase?**

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The Indian pharmaceutical industry is undeniably going through a very dynamic phase, and I expect that the Indian industry landscape will experience significant transformations in the coming years.

Since the Indian and international regulators have been continuously upgrading their qualifying requirements, whether they relate to clinical trials, GMP, or other certifications, this increasing regulatory pressure could further nurture the industry's consolidation worldwide. The latter will most likely be triggered by the industry's largest players at the initial stages as they invariably hold large financial resources, and this advantage will unmistakably result into upgrading the existing as well as acquired assets to ensure they meet the highest regulatory standards.

Although late towards acknowledging the importance of the healthcare sector, the Indian government has recently increased its commitment and outlay to our country's healthcare ecosystem [*in 2017, public spending for healthcare stood at around 1.25 percent of the Indian GDP* Ed]. While announcing the Union Budget for 2018-19, the Finance Minister Arun Jaitley announced a new, ambitious National Health Protection Scheme, which will 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. This program could very well mean a giant step towards the setting up of a broader social security system in India, and it will no doubt significantly benefit the domestic pharmaceutical companies.

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Nevertheless, over the past years, few big Indian companies as well as some mid-cap players have steered a large share of their efforts towards conquering regulated markets, and they have recently realized that for them also the latter were becoming increasingly competitive. As a result, these companies have been looking at swiftly entering various new markets in order to find ways to compensate price erosion in regulated markets.

In the grand scheme of things, India proudly stands as the fastest-growing large economy in the world, and given the country's 1.2 billion inhabitants, it makes no doubt that our domestic market will gain an increasing importance in the strategies of domestic companies. In this regard, we can expect that the dynamism of the Indian market will bring some fresh wind in the sails of the domestic industry and help it conquer market shares abroad moving forward.

**Looking at the latest data provided by Pharmexcil, we however see that total exports of pharmaceuticals (including APIs, finished, and alternative medicines) decreased by 0.47 percent in FY2016/2017. Would you say this poor performance was exceptional or, in your view, the Indian pharmaceutical industry is truly at a turning point?**

In order to do an in-depth analysis of the same, the key parameter to take into account is that a significant number of countries have recently decided to boost the domestic production of locally consumed drugs. Just to give you an example, Russia's Pharma 2020 Strategy aims to reduce the dependence of the Russian economy on imported pharmaceuticals with the ultimate objective to see domestic production increasing from 28.5 percent in 2016 to 75 percent by 2020, according to Russia's Prime Minister Medvedev. This is the reflection of a truly evolving global trend affecting almost all countries, and Indian companies are no exception to this phenomenon and must embrace this new model.

In this regard, I expect that the years to come will witness an increasing number of foreign acquisitions by Indian companies, as well as an unprecedented upbeat and eagerness to forge strategic alliances with national and/or international producers. This new paradigm will emerge as a true challenge vis-a-vis the export-based strategies followed by Indian companies until now.

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**Indian pharmaceutical exports were worth around USD16.84 billion in FY2016-2017, accounting for roughly 6 percent of the country's total export of goods of USD275.8 billion. In your opinion, what essential steps the government needs to take to further accelerate the development and consolidation of Indian pharmaceutical companies?**

India's economy has been growing at an eye-catching pace since the advent and during the tenure of Honorable Prime Minister Narendra Modi's government, and he is rightly praised and credited for implementing difficult but long-delayed reforms. In this regard, Prime Minister Modi probably stands tall and distinguished as being the most dynamic Prime Minister that India has ever had, and we can clearly feel a willingness in him to listen to the industry's voice, assess the needs of the domestic ecosystem and provide adequate support and protection to local industries.

With regards to the pharmaceutical industry, India holds an incredible number of modern, state-of-the-art national assets, such as the National Biological Center, for example. In parallel to the research work conducted by these national R&D centers, Indian companies have been investing huge resources in developing monoclonal antibodies and biosimilars. However, while considering the long development period and registration timelines that characterize these products, the fact the industry continues duplicating such R&D investments across the Indian ecosystem becomes debating point.

In this context, leveraging these cutting-edge national assets to develop public-private partnerships could accelerate the country's ambitions and prospects to develop more complex products and avoid the duplication of R&D investments across the industry and this is clearly an option that the government should consider moving forward.

**Set up in 2002, BDR Pharma stands as a relatively young company within the Indian pharma landscape. What motivated you to set up a new pharmaceutical company after having co-founded and propelled the international development of Hetero Drugs?**

I co-founded the HIV/ARV-focus company Hetero Drugs in 1993, at the height of the HIV/AIDS epidemics. We quickly started working very closely with the Brazilian government and health authorities, and our joint efforts in this country led to the development of one of the best HIV programs globally. Overall, Hetero Drugs was acknowledged as world leaders for supply of anti-retrovirals to Latin America, the Middle East, Sub-Saharan and Africa, thereby saving millions of lives of HIV-infected patients from the jaws of death.

However, my life took a turn for the worst when my father was diagnosed with multiple cancers and was literally fighting it over a span of five years. While accompanying him along this frustrating journey, I realized that exorbitant prices of cancer drugs were leading a large number of Indian families to a financial ruin, in a desperate attempt to save their loved ones. I met one of those families while waiting in a hallway for my father to finish a round of chemotherapy: the father was a taxi driver and the mother worked for an insurance company. They had sold and lost everything they had including their house to pay for the treatment of their young son's leukemia. They probably were aware that his chances of survival were extremely low, but this fact did not prevent them from trying everything they could to save him.

After having dedicated over ten years of my life to the fight against HIV/AIDS, seeing the ordeal of the above unfortunate family and many others prompted me to shift my efforts to the cancer area. In 2003, cancer was still a relatively underdeveloped therapeutic area in India, primarily because of the lack of awareness about the seriousness of the disease and most importantly the lack of early detection due to limitations in the available technology and the overall low spending on healthcare by the successive governments and the industry. From a pharmaceutical standpoint, it

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was therefore a rather unrewarding sector, with only a few Indian companies operating in this segment, with over 80 percent domination by the MNCs.

Therefore, I decided that BDR would focus on anti-cancer products, with a specific emphasis on much needed molecules targeting the most prevalent cancers in the country – breast, prostate, lung, and liver cancer. Our philosophy continues to be simple: to make cancer drugs affordable and accessible and save as many lives as possible, which otherwise was a distant dream almost a decade ago.

**In this noble endeavor to develop affordable oncology products, what would you highlight as some of BDR's main achievements?**

Once the area of focus of BDR was clearly defined, I identified highly needed cancer originators with no generics alternatives and started working on BDR's own formulations. Barely nine months after having started our activities, we were able to bring to the Indian market – at the price of USD4 per vial – the molecule used to treat my father, for which I was paying over USD1500 per injection.

While intensifying our efforts in the cancer area, I expanded BDR's scope of activities to the intensive care field, where patients are often affected by nosocomial infections. We therefore developed an affordable version of the best antifungal in the market, and BDR became the second company after Merck (and the first generics company) to bring *Caspofungin* to India – for almost one third the price of the originator. As a result, we rapidly gained a 90 percent share in this niche product and continue to hold this position.

On another note, many external observers might not be aware that out of India's total population, more than 100 million are senior citizens, and this number is set to triple by 2050. Prostate issues affect around 55 percent of elderly men; since many of them are also afflicted by and have to cope with other old age related chronic diseases and/or infections, undergoing surgery is the last option for them, which renders indispensable to go for other, safer treatment options. In this context, I identified that most Indian patients could not access Janssen's *Abiraterone*, whose cost ten years ago was as expensive as around USD15,000 per month. Beside this prohibitive cost factor, Indian patients had to contend with importing the product directly from the US, after having received specific authorization from the American company. This played a dual devastating blow to the suffering Indian patients – one by way of excessive price and the other because of the unpredictability of the company's delivery timelines. Again, BDR was the first Indian company to introduce a generic alternative of *Abiraterone* at a substantially discounted price tag of around USD300 per month of treatment. While Janssen India used to import barely few hundred bottles (each bottle has 120 tablets) per year prior to the launch of our generics (which was far below the actual market demand), BDR today produces over 36,000 bottles of *Abiraterone* per year, catering almost to the entire market demand.

In the grand scheme of things, BDR has always focused on first-to-market generics targeting those molecules which have huge potential but are financially unaffordable and whose accessibility is never a certainty. In the process, we need to ensure that our products are extremely affordable considering the fact that Indians' average purchasing power is much lower than in the US and European countries, so our product prices have to be within reach of the suffering masses. Thus our twofold criteria has always been – accessibility & affordability – with regards to the products we introduce in the market. During this whole process, our R&D plays a stellar role and stands as a strategic focus of our company, both for APIs and finished formulations. Looking forward, BDR's goal is to develop target-based therapies for existing oncology drugs, with improved toxicology and bioavailability profiles. In the meantime, we are moving our R&D model towards more complex, high-

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end molecules for which there is no existing generics alternative in the local market. In the oncology and critical care segments, our objective is to build an integrated pharmaceutical company, which would provide us with a great competitive edge when it comes to developing affordable medicines while generating enough profits to allocate more funds to larger R&D activities.

**In the domestic market, you have been partnering with some of the largest Indian companies to market BDR's products. Given the sustained growth and ever-increasing attractiveness of the Indian market, do you plan to set up your own marketing and sales channels?**

We have our own marketing and sales division in place since 2015, and it is doing a tremendous job since then. However, since India is a country of over 1.2 billion people, it requires building a sales force of at least 25,000 medical reps to guarantee a satisfactory coverage of the whole country; this being a challenging and marathon task, we will need more time to accomplish it – especially in a highly complex therapeutic area such as oncology.

Although we are tirelessly working on developing our own ethical division, I always look in the meantime at like-minded people and companies to partner with us through co-marketing or co-licensing agreements, in order to ensure all patients across India can access our life-changing products. As a matter of fact, this is already a reality in BDR with a number of leading pharma players joining hands with us and co-marketing – niche – life saving products.

**Leveraging your international expertise, BDR Pharma has already built for itself a strong reputation in emerging markets, and you are now pooling resources to enter Europe and the United States. How do you plan to overcome the fierce competition that has recently been driving generics prices down in these strategic markets?**

To cope with price erosion in Europe and the US, we have decided to focus only on those products in which we hold a competitive edge and we are end-to-end integrated. Overall, we are well aware that we will face a fiercer competition in the US than in Latin America, but we hold several strong assets to overcome it. First, we are a privately-owned company, which allows us to operate in a faster and more effective way than publicly listed, big generics companies. In the same vein, we do not face any pressure from stakeholders either, which provides us with a greater flexibility when selecting our markets and the products we decide to launch in regulated markets.

Finally, we have always put strategic alliances at the core of our international strategy. BDR's ability to continuously introduce new molecules and its professional integrity in India and in some strategic emerging markets have significantly strengthened our international reputation, prompting some large players to engage in strategic partnerships with us. To name a few, we have already entered into co-development agreement with one of Brazil's powerhouses and we are partnering with a local strong player in the CIS area. Depending on a given market's orientation and dynamics, these alliances take on various forms and shapes, ranging from co-development partnerships to the set-up of joint ventures. Looking forward, we plan to replicate this approach to regulated markets also. We have already initiated this process in Europe, where companies have already reached out to BDR Pharma to leverage our formulation and manufacturing expertise, which in turn emerged as our first entry into European markets.

However, we are absolutely clear on one point: we do not want to be simply tied down operating as a mere contract manufacturer on behalf of international partners – be they in regulated or non-regulated markets; our overall strategy is either to be a co-development partner or at the best to set up joint ventures. My philosophy is not to enter a given country and engage in a price war – as most Indian companies did in the past. To the contrary, our larger plan is to find strategic partners who could bring our R&D-based, value added products to the next level.

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## What is your final message to our international readers?

Healthcare affordability no longer stands as a crucial issue exclusively affecting emerging countries, and many advanced countries have recently taken a stance on public spending. In this context, BDR Pharmaceutical is ready to leverage complex chemistry and develop highly needed products to provide patients around the world with a greater access to affordable medicines. In our commitment to ameliorate and alleviate the sufferings of patients around the world over, we are always driven by our life long philosophy of “accessibility and affordability”. This commitment is our legacy, which my family will endeavor to fulfill and carry forward for the coming generations as well.

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