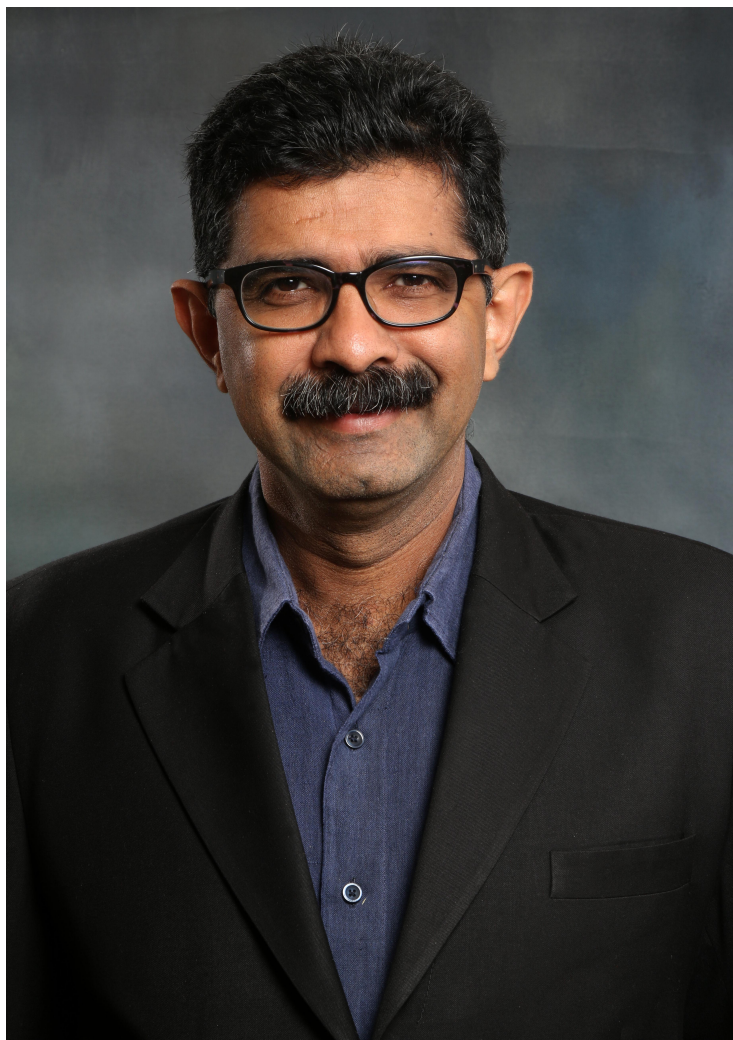


'Cipla's investment will help create first biocluster in South Africa'

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'Cipla's investment will help create first biocluster in South Africa'



Singapore: Although currently small and focused on few diseases, the biosimilars opportunity is all set to grow, thanks to the unprecedented patent cliff and rising healthcare costs. Biosimilars are a clear potential for players in emerging Asian countries as there is a need to broaden healthcare coverage with limited budgets.

Several Asian companies have been increasing their focus on biosimilars, terming it a long term prospect. Recently, Indian pharmaceutical giant Cipla announced that its proposed biotech subsidiary in South Africa will invest just over R1.3 billion into the country's first state-of-the-art biotech manufacturing facility, for the production of biosimilars. As per the company's

release, the facility will have the necessary design capacity and capabilities and will seek regulatory approvals to supply both to the local market and to export into the rest of Africa and Europe.

The factory, which will be located in the Department of Trade and Industries Special Economic Zone of Dube Tradeport in Durban, will manufacture biosimilar drugs made from living organisms and used in the treatment of cancer and other diseases. At full capacity, the facility will create up to 300 jobs, primarily in the engineering and biological science fields. This facility will run independently.

This is not Cipla's first foray in the African market. In 2013, Cipla had acquired South African drug firm MedPro, one of its first large foreign acquisition and has been ramping up presence in the African nation since then. Last September, Cipla had made an announcement that all its biologic business will be consolidated under Cipla Biotech, which will focus on drug development in cancer, respiratory, and diabetes treatments.

The company also said in its release that, in South Africa, people without access to private insurance cannot afford biologic medicine due to the very high prices of the innovator molecules. Currently about 1-in-50 patients in Africa have access to biologic medication. Cipla further added that with this new venture they are striving to reduce this number to about 1-in-5 cancer patients through the production and supply of biosimilar medication at an affordable price.

BioSpectrum Asia Magazine spoke to Mr Chandru Chawla, head of Cipla New Ventures to elaborate on Cipla's plans for the facility, the biosimilar opportunities, challenges and their expansion plans for the future.

Excerpts:

1. Cipla is strengthening its base in Africa with its new biosimilars facility. Please tell us more about this facility.

This will be a modular facility supporting our strategy of small footprint, distributed manufacturing and will cater to international markets as well. The facility will be located in the Department of Trade and Industries Special Economic Zone of Dube Tradeport in Durban and will manufacture biosimilar drugs made from living organisms that would be used in the treatment of cancer and other diseases. Construction is scheduled to start in early 2017, with full operations expected to commence in the third quarter of 2018. The manufacturing base here in South Africa will allow opportunities for supply chain partners and related companies to get involved. With this investment we aim to create the first bio-cluster on the African continent.

2. In your opinion, how important are biosimilars for the South African market?

Biosimilars are affordable option for healthcare across the developing world, and mainly in countries like South Africa the penetration of biologicals is generally is 2-5 percent. This offers enormous opportunity for those who take a quantum leap to bridge this. Biosimilars are a clear potential for players in developing countries as there is a need to broaden healthcare coverage with limited budgets. The growing demand for affordable biosimilars by patients will see it grow exponentially not only within Asia but across the globe. The affordability factor has to come down by a factor of 5 - 10x in developing world for a significant breakthrough.

3. What are your key initiatives for the Indian and the African market for the next few years?

Our products will start being filed in Africa from 2018 onwards and this unit will cover some other markets as well.

4. What are the major challenges that you foresee in commercializing biosimilars in the African market?

Unlike generics, commercialization of biosimilars poses many challenges. The development of biosimilars is a long process that is fraught with risks and costs. In Africa, mainly, we will have to target the demand and supply points for better commercialization. At demand level, we will need to create appropriate levels of awareness. At supply level, we will endeavour to work with public, private and NGO stakeholders to create an appropriate ecosystem that can influence access to these affordable medicines and benefit many people, thus reducing healthcare costs.

5. Please share your thoughts on regulatory hurdles in the biosimilars space.

Lack of harmonization poses significant challenges in front of biosimilar developers, however now the world is harmonizing towards a regulatory culture that will recognize strong characterization efforts and smartly designed clinical trials and encourage indication extension.

6. *In your opinion which are the most prominent countries in Asia poised to ride successfully in the biosimilars wave?*

Currently, South Korea and India are attractively poised. Former is a bit ahead in terms of learning curve and talent.

7. *What makes biosimilars an attractive investment option?*

There is a wide gap between the numbers of patients who need these and the numbers of patients who can access them today. Also most of the developed world can save billions of dollars in health expenditure through use of biosimilars.

8. *Could you please talk about your product portfolio in depth?*

In this facility, our focus will be initially on cancer medications. Our first product, cbt 124, is a bio similar of avastin.

9. *Globally which are the other emerging markets that you plan to target? Throw some light on your expansion plans.*

We think globally - one product, one quality. Our focus is global - in wave one we plan to target India and other emerging markets of Asia, Africa, South America, followed by Europe, the US and Japan.