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Building On 100 Years In India: The Next Big Things On GSK's Horizon

by Anju Ghangurde

GSK's India chief talks to Scrip about new category creation in adult immunization with Shingrix seeing strong uptake, Nucala and Trelegy's trajectory and oncology assets set for debut as the company steps into its 100th year of operation in the country. GSK expects to continue to transform its operating model as things evolve, he indicates in the concluding part of this interview.

When <u>*GSK*</u> (then Glaxo Laboratories) introduced the infant formula milk brand Farex in India way back in 1924, it was the nutritional needs of infants that drove the decision. The baby food brand, which has long since changed hands, went on to become a household name in the country.

Hundred years down the line, GSK hopes to make a material impact at the other end of the spectrum – healthy aging. The UK-headquartered company expects adult immunization to play a critical role in preventive healthcare as life expectancy inches upwards in developing nations like India.

"We are working very closely with healthcare practitioners/hospitals, to set up the adult vaccination ecosystem, because that will be the real game changer. But we also believe it's not a 100-meter sprint, it's an endurance sport," Bhushan Akshikar, managing director, <u>GlaxoSmithKline Pharmaceuticals Ltd.</u> told Scrip in an interview. (Also see "<u>100 Years In India –</u> <u>GSK's Secret Sauce To Not Just Stay Relevant But Thrive</u>" - Scrip, 18 Sep, 2024.)

Striking early momentum for its shingles vaccine Shingrix suggests that things may be moving in the right direction, though Akshikar underlined that companies like GSK will need to stay



Pink Sheet, 12 Jun, 2023.)

GSK's India chief also outlined how things are poised in the respiratory business, another other core growth prong, in this second and concluding instalment of the interview. (*See side box*)

Quality Of Life Equally Important

There some big picture changes underway driving pharma's upbeat stance on adult immunization. With a population of about 1.43bn and improving life expectancy in India, the preventive medicine theme is gaining traction, including on the policy front.

By 2036, the population of India is expected to go up to 1.52bn, with a minor uptick in the percentage of the female population to 48.8% versus 48.5% in the 2011 Census, government data indicated earlier this year. Life expectancy has been steadily increasing since 1990 and stood at 68.6 and 71.4 years for males and females respectively during 2016-20 and

committed to unlocking and creating value, because "mindset change and category creations are always arduous tasks".

Vaccination in markets like India has long been associated with the pediatric segment and more widely Akshikar noted that for anything in the preventive space, the Indian consumer is generally "very value conscious", ostensibly for the right reasons. For instance, unlike in the West, not many adults in India opt for an annual flu shot for various reasons – the immunization rate for this category is estimated at less than 1- 1.5% in the country. (Also see "<u>GSK's Walmsley On US v. EU COVID-Flu Combos,</u> <u>RSV Branding, And Investing In Infectious Disease</u>" –

Nucala, Trelegy Trajectory

Beyond the vaccines thrust, GSK has also seen significant traction with its respiratory assets.

The newer respiratory portfolio comprising Nucala (mepolizumab) and Trelegy Ellipta, the first single inhaler triple therapy for chronic obstructive pulmonary disease (COPD) in India, reported growth of 57% in the fiscal first quarter ended 30 June 2024, bolstered by improved patient access.

Nucala, which is indicated for severe eosinophilic asthma and certain other eosinophilic driven diseases, comes with the need to segment and identify patients who can most benefit.

Bhushan Akshikar, managing director, GlaxoSmithKline Pharmaceuticals Limited, underlined that Nucala isn't a product that "we just go and promote", because the firm is

is expected to reach 71.2 and 74.7 years respectively by 2031-36.

"When you look at where India will be by 2030-2035, with that life expectancy, the quality of life will be equally important. There are large number of people who want to take charge of prevention and wellness themselves," Akshikar maintained.

The devastating COVID-19 pandemic too played a role in shining the light on the value of vaccination more widely.

Akshikar recounts that till COVID, "vaccines were equal to babies/infants".

"But with COVID, things changed, even in a country like India, where most people took at least two doses, if not more, to protect themselves against the infectious disease. That's a significant change for our market now," the executive said.

Government policies too reflect a thrust on quality of care, focus on emerging diseases and investing in "promotive and preventive" healthcare. Companies like GSK see a central role for themselves in the emerging scenario.

Pediatricians As "Default Vaccination Point"

Akshikar believes GSK has what it takes to contribute to healthy aging via the adult vaccination plank and the company appears prepared for the long haul.

GSK's India chief referred to how in the area of pediatric vaccination 30-35 years

mindful that it is indicated only for severe eosinophilic asthma cases.

"But the benefits that we've seen when patients' lives get transformed when they've been on the therapy, and we've clearly brought data points now, even in India, to show that for severe asthma, you can actually remain in remission. So that's one of the reasons why you see that uptake consistently going up," he explained.

Nucala reported a revenue growth of 66% in India in FY2023-24, with an estimated 1,700plus patients benefiting since the product's launch.

GSK has also unlocked value with Trelegy, launched in 2022, and while there are wellentrenched players on the Indian respiratory market, the company expects these two assets to make an impact on the large respiratory canvas in the country, where the air quality index is expected to remain a concern in many cities.

"If you see the respiratory market, the oral corticosteroids, the inhalers and now the single inhaler triple therapy, clearly, lot of physicians see value in prescribing one device as opposed to giving multiple devices, and that's where we are really seeing a huge uptake,"Akshikar said.

Between Nucala and Trelegy "every single month, we continue to make progress", he added.

ago, there was no vaccination ecosystem in India for infants and babies and their caregivers or parents. People had to essentially rely on municipal/government hospitals.

But the launch of GSK's hepatits B vaccine Engerix B in 1982 brought about a significant shift in the ecosystem; today people with children don't have to worry about where to get access to those vaccines, because pediatricians are the "default vaccination point". Trelegy continues to be one of the fastest growing brands in the single inhalation, triple therapy segment. In FY203-24, Trelegy saw revenues surge 133% in India, albeit likely on a smaller base.

"Both these assets didn't exist four or five years ago, and this year, we are hopeful that we should create a portfolio of at least INR750m (\$8.9m) if not more, with these two assets," GSK's India chief declared.

"That's largely because of the efforts that

were put in by companies like GSK, and that's something that we are committed to," Akshikar asserted.

Currently India has at least 10,000-12,000 pediatricians in the private set up who take care of the vaccination needs of a birth cohort of an estimated 3 million babies annually.

GSK has about 24% market share and continues to be the top ranked company in the self-pay pediatric private vaccine market. Older products like the pneumococcal vaccine Synflorix continue to be an important part of the portfolio, but may have bottomed out given "a cohort that's increasingly predisposed to taking that vaccine in the national immunization setting". That segment has seen the arrival of *Serum Institute of India Pvt. Ltd.*'s indigenously developed pneumococcal vaccine, Pneumosil.

"In the private setting, we are holding fort. I don't think we will go back to the levels that we had maybe six years ago, but I think over the last 12 months, we are holding steady at a certain point," Akshikar pointed out responding to a question on the outlook for Synflorix.

While Synflorix remains "a very important asset", the company has also made strategic choices in terms of which brands to focus on. For instance, there's a clear thrust on ensuring that the hexavalent vaccine (Infanrix Hexa) is a mainstay, apart from the continued focus on preventing hepatitis and meningitis, he added.

Globally, GSK has indicated an intent to continue its focus on preventing pneumonia in the pediatric population and the 2022 acquisition of <u>Affinivax, Inc.</u> gave it access to next-generation pneumococcal vaccines and the firm's novel Multiple Antigen Presenting System (MAPS) technology. (Also see "<u>GSK Spies Pfizer Challenge With \$2.1bn Vaccine Company Acquisition</u>" -



Scrip, 31 May, 2022.)

New Vaccinators

GSK hopes it can replicate the success in the pediatric segment to create an adult immunization ecosystem in India so that a large proportion of patients are safeguarded against vaccine preventable disease.

With the debut of Shingrix in April 2023, Akshikar noted that many physicians who hitherto were "never vaccinators", had started vaccinating.

"For us, that is the real metric, which means you are actually making prevention an equally important part of the armamentarium of that healthcare practitioner, as opposed to just focusing on treatment," he explained.

Shingrix was among the top 10 new product introductions on the Indian pharma market in the past 12 months as per IQVIA data for February 2024.

While a large part of HCP time goes into discussing treatment options amid the sheer volume of patients, increasingly, more and more physicians understand the importance of spending time on talking about prevention, counseling patients.

"Today, we have at least 1,500 healthcare practitioners who had never done any adult vaccination, but who are consistently doing so now. That's the kind of change I'm talking of," Akshikar added.

"Where we want to put our energy and focus is to really ensure that the adult vaccination ecosystem creation is an area which is well understood, but more importantly, we create those conversations between patients and healthcare practitioners."

Shingrix Momentum

That, since the need for preventive healthcare from the patient's perspective is also not all clearcut – after all in the patient's mind it's something that may or may not happen.

That's where data can make the difference – for instance, new long-term data show Shingrix continues to provide high protection against shingles in adults aged 50 and over for more than a decade. The data from the ZOSTER-049 long-term follow-up phase III trial also showed vaccine efficacy remained high at 82% at year 11 after initial vaccination.

"Using, again, science led promotion to talk about how the vaccine can help. Sometimes herpes can lead to several complications, like post-herpetic neuralgia..... really bringing therefore the right conversations in the doctor's chamber is the focus right now for us," Akshikar explained.

The Shingrix debut is also distinct in that it's the first time a vaccine was launched in more than seven specialties in India. A number of factors can raise the risk of developing shingles, including advancing age and immunodeficiency or immunosuppression, as well as other chronic conditions such as chronic obstructive pulmonary disease (COPD), diabetes mellitus, and asthma.

"There's enough scientific data and evidence to prove that diabetics are at a higher risk. Therefore, you have specialties like diabetalogists, rheumatologists, and there are also some family physicians who really understand the value of immunization," GSK's India chief stated.

These efforts appear to be paying off, at least going by early trends. An estimated 60,000 adult patients have been vaccinated with Shingrix since its launch, implying a promising sales trajectory.

"If you think about a new category which didn't exist, that's the kind of growth platform that we want to build. And again, it's a part of our re-invention. It's a part of how we want to continue to repurpose and reinvent our business model, continue to transform our operating model," he asserted.

New Products Lined Up

Such early groundwork in adult vaccination is also important with products like the respiratory syncytial virus vaccine (Arexvy) in the wings. GSK has submitted an application for conducting a Phase III clinical study in India with Arexvy in older adults to support its marketing authorization application in India. Trials are expected to commence next month in India.

GSK has also obtained marketing authorisation in India for oncology assets including Zejula (niraparib) and Jemperli (dostarlimab concentrate solution for infusion) for the maintenance treatment of ovarian cancer and the second line treatment of endometrial cancer, respectively.

Akshikar indicated that the company is in the advanced stages in terms of progressing the commercial model of the launch of these oncology assets.

More importantly, Akshikar highlighted that India is increasingly part of several GSK global clinical trials. (Also see "<u>India</u> <u>Trial Waivers: New Drugs, CGTs Cleared In</u> <u>Specific Countries To Qualify</u>" - Pink Sheet, 12 Aug, 2024.)

"We have about 19 trials happening right now in India, including of assets like Blenrep (belantamab mafodotin-blmf)

Foreign Firms Not Fatigued In India, Game For 'New Things'

By Anju Ghangurde

28 Mar 2022 Senior management executives of Roche,

used to treat multiple myeloma, which is currently indicated for second line multiple myeloma. Globally, there's a trial ongoing for first line as well. So that will open up a whole new opportunity for us in the oncology segment," he explained. (Also see "*India Clinical Trials Scenario: Leaders From Novartis, IQVIA, PwC Signal Winds Of Change*" - Pink Sheet, 23 May, 2023.)

Bayer, AstraZeneca, Pfizer and Novo Nordisk in India signal momentum in product launch and clinical trial activity, belying apprehension of wider cutbacks by foreign firms in the country, though one executive stressed that "tried and tested models" may not work in the largely self-pay market.

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He sees many such assets, "as appropriate", getting commercialized in India.

"We have a strong foundation which will still continue to be relevant when I look at the prognosis over the next five to 10 years, including our dermatology business, for example, which is still very relevant and one of the largest businesses that we have," Akshikar added.

GSK's India chief said the broader task on hand, though, is to bolt on these high growth areas on top of the foundation of the 100 years of commercial operations in India.

"That's how I see the business evolving. Obviously, we'll have to do both. It's like tuning the engine of a car as you're driving. We'll have to learn to be more efficient in the operating model that we have. But of course, completely reinvent with the new therapy areas as well," he said. (Also see "*Big Pharma Restructures Commercial Teams In India*" - Scrip, 6 Dec, 2022.)