"We are trying to stay away from the *me too* business strategy"

DR PIYUSH GUPTA

"In GNH India, we are helping the local manufacturers to develop true generics of latest drugs by providing comparators hence supporting clinical research process," says **Dr Piyush Gupta, Associate Director, GNH India.** Excerpts from an interview he had with Mahesh Kallayil.

Could you please tell us about GNH's offering to pharmaceutical industry?

In trade terms, GNH is into specialty wholesale. We are wholesaler specialised in distribution of orphan drugs, rare drugs, life-saving drugs, etc. The government statutory term for our domain is merchant exporters. While 80 per cent of our business consists of exports, 20 per cent focus is on import and domestic supply within India. With close to two decades of experience, GNH India has evolved from traditional logistics to fully integrated supply chain solutions. We are one among few Indian companies who has WHO-GDP certification. We are the only Indian wholesaler who has registered with several ministries of health in International markets.

We ship to over 180 countries and carry over 1,35,000 product lines. Rather than setting up a capital heavy set up of manufacturing plant, we have tied up with several reputed manufacturers. This enables us to supply a wide range of medicines. We are focused as a one stop shop for pharma. Our clients call us the supermarket for medicines as they have been able to find all their requirements at one place.

In GNH India, we are helping the local manufacturers to develop true generics of latest drugs by providing comparators hence supporting clinical research process. During clinical trials, comparators are needed to assess development process at every step of progress. Comparative medicine are very costly and rare, so finding a right comparative medicine is like finding a needle in haystack. We are helping the Indian companies to get the right comparators at competitive price.

GNH India is one of the few companies to supply a pedigrees dossier at the time of comparator supply. Each and every fact pertaining to the drug needs to be documented in a dossier. From where it was purchased, the purchase invoice, transport traceability, temperature, where was it stored, the custom duty receipt everything needs to be documented and given as a dossier along with the comparator.

What are the most demanding areas of clinical trial operations nowadays?

The first most demanding area is getting patients. India being the second largest nation in terms of

population, yet we are shortage of patients. This is because the rules and regulations are convoluted.

The second largest problem is the availability of comparators. We do not have original comparators available here, easily. To bring one comparator it takes us two months. There is so much paper work involved.

How significant is the role of logistics and SCM in the pharma industry?

Logistic is one of the most important factor for pharmaceutical industry. Pharma cold chain is complicated. All the biologics which are living cells are temperature sensitive. We have to be very careful while exporting these biologics. The carton which we use for exporting biologics itself costs around ₹ 12,000 and comes from Singapore. We are using validated cartons in our warehouses for transport of biologic product.

There is so much emphasize on logistics today. The government wants data loggers in every shipment. When we are sending medicine abroad, the ministry will ask for data logger, where temperature in transits can be recorded. That is how important logistics is becoming. Most of the pharma company focuses exclusively on pharmaceuticals and ignore logistics. In India, logistic is outsourced. Our company is one of the few to have in-house specialty logistic expertise in India.

How supportive is the regulatory landscape for research and clinical trial in India?

Regulation is a learning experience from the mistakes of past. In the past, regulations were flexible. Lot of things went wrong. The industry misused the leniency. Lot of foreign companies came, did illegal trials without the knowledge of patients. Because of these, now the regulations are tilted in the favor of patients. So, I can't say that regulations are not supportive. There are lots of checks and balances, it is pretty complicated and is not easy, due to which lot of clinical trials are getting delayed in India.

How do you plan to leverage on Make in India campaign?

Pharma industry can be flurished in a country which has a petrochemical industry. Most of the chemical entities are derived from petrochemicals. Second, you need qualified people. In India, we have both the raw material and the people. We have the history; we have the companies which have taken us globally. India has become a pharmacy to the world at least in generics. The world expect us to fulfil their pharma requirement. The world has started to expect India be the supplier to generic.

Now, the same thing if we could leverage to biosimilar, India will become pharmacy hub to the world. In generic manufacturing, we have hit the ceiling. Our next frontier should be biosimilars and biobetters.

If you check the product list of main Indian pharma companies, you will barely see any difference. Price has become selling point in Indian market. India's export value has come down while volume has gone up.

Sadly in India, we have something called 'herd mentality'. We replicate products which are doing well in market. We don't want to add some value to it. What is the point in copying someone's innovation and selling it in low price? When you add a value to it, you are adding pride in it and making the product even better. But sadly we don't have any company in public domain which is working on biobetters.

The cheap generics no longer sell. Human tendency is not to go for the cheap. On contrary, humans look for value. The selling point, the USP, cheap is not working anymore. It worked for the last 10-20 years because there was a gap in the market. Today, even the companies from Pakistan (Getz Pharma), Bangladesh, Jordan (Hikma) are manufacturing generics. India's monopoly in generic market has come to an end. Now, future lies in 'betters'. The generic has to become better by adopting new drug delivery technologies.

In your opinion, what are the Strengths, Weaknesses, Opportunities & Threats for the Indian Pharma companies?

Our manufacturing bases are our strength. With regard to weakness, everyone is trying to sell the same product at same price. We have now reached the end of the road in this strategy. Almost every biosimilar developed in India is being challenged in courts by the innovators. The reason is we are trying to use the same formula of generics to biosimilar. Since 1970's, we are in the mind frame of generics. Generics are the photocopy of original chemical entity. This cannot be applied in biosimilar. Also, now even the innovators are ready to sell their drugs in half price.

Opportunity - The world is our market. Our manufacturing facilities are registered worldwide. This gives us access to every country. Threat is ourselves. We need to work on innovation.

In clinical trial, strength is easy availability of large volumes of drugs/comparators. Weakness is the lack of awareness, that the medicines available in India can also be used as comparators.

By 2020, 100 billion worth of drug is going off patent. If we do not recognise that biosimilar and generic are two different things, we will lose this opportunity.

The word here is 'similar' which we are not getting right. In generic it can be 100 per cent replica, in biosimilar it could be 98 per cent. The stress here is 'similar' in result, not 'similar' in molecular structure.

From supplier point of view, we are already working on it. We are trying to spread awareness through interaction with the press, white papers and interaction with the government.

The general thinking among Indian manufacturers is 'reactive'. If they get a letter from USFDA, then only they will try to address the issue. If we really want to grow as a globally competent model, we need to be 'proactive'. We need to correct our fault before a regulator points out. When a regulator catches, it is called a 'Show cause notice', when we correct it ourselves, it is called as an 'amendment'. We need to bring 'proactive' approach in quality.

The general thinking among Indian pharma manufacturers is reactive. We need to bring proactive approach in quality.

How do you intend to steer the growth of GNH India in the years to come? Please detail about your future plans in terms of strategic alliances, capacity expansion, products launches, investment, etc.

We are trying to stay away from the 'me too' business strategy. Our growth strategy is divided into several verticles:

A) Domestic Supply chain solution: WHO GDP certified domestic supply chain solution - today's pharma logistics is outsourced to regular logistics companies with no knowledge about recalls, ADRs, or pharmacy vigilance. We plan to offer an end to end solution to manufacturer from the factory gate to the retail shop, all under WHO GDP compliant process. This has over USD 2 billion market in India itself.

B) Domestic Comparator supplies: Any development process consumes comparators worth USD 18 - 20 Million. Domestic comparator market is estimated to be over 500 Million USD annually. We are working to create awareness that there are Indian companies too which can supply comparators or references drugs at cost effective prices.

C) Domestic Orphan Drug supplies: This is a neglected therapy area in India and estimated to about USD 200 Million annually. We are one of the early starters in this area and plan to build a lead and continue maintaining it.

D) International Markets - Global Speciality Wholesale: Global Pharma market is estimated to be around 340 Billion of which 80 Billion is Wholesale Trade. Again, we are among the first few or the only professionally run, organised global wholesaler operating from India, supplying medicines to over 180 countries globally. We target to capture a minimum of 10 per cent of this global pie in next five years. ■