

**“We keep quality at the forefront of everything that we do”**

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**Piramal Critical Care, a division of Piramal Enterprises, is a global leader in the field of Anaesthesia with a portfolio of inhaled and intravenous Anaesthesia and pain solutions that are used primarily in hospitals and other institutions.**



In an interaction with BioSpectrum Peter DeYoung, the CEO of Piramal Critical Care, who is a member of the Piramal Pharma Operating Board and a member of the Board of Piramal Imaging SA shared his views about the company’s expansion plans and maintaining compliance to US FDA rules.

**Piramal Critical Care is the world's 3rd largest producer of inhaled anesthetics, what plans you have to reach the no 1 position?**

We are the world's third largest producer of Inhaled Anaesthetics with a global market share of 10 per cent and the only company with the complete inhalation anaesthetic product portfolio, but we have a long way to go before we could contemplate a number one position. We are also a leader in intrathecal spasticity products. Our products are sold directly or through our network of distribution partners in over 110 countries across the world, with widespread availability in the US, Europe, Japan and a number of important Emerging Markets, including India.

Piramal Critical Care follows a strategy that is a combination of both organic and inorganic growth. We aim to build on our strength in the hospital and institutional segment by further augmenting our generic hospital pharmaceutical product portfolio and by increasing the market share of our current products. In order to ensure the long-term sustainability of our business, we are pursuing profitable growth in our inhalation anesthetics business and our hospital portfolio overall. With that in mind, while we believe we have headroom to increase volume and market share with each of our current offerings, it also needs to be done in the context of profitability. Thus we are pursuing a balanced strategy of profitable market share growth coupled with efforts to broaden our basket of offerings to further increase our relevance to our customers.

**After acquiring drugs from Mallinckrodt and Janssen, are you planning any other acquisition or are you in any talks?**

As a company we have a long history of pursuing both organic and in-organic avenues in parallel to driving profitable growth. However, given the size and importance of the transactions, one of our main focus areas over the last year has been to successfully integrate the products that we acquired from Janssen in October 2016 and Mallinckrodt in March 2017. Now that we have made substantial progress in these important segments, we are once again looking at organic as well as inorganic growth opportunities.

In the coming years, we foresee a number of exciting growth opportunities for Piramal Critical Care. As mentioned earlier, with less than 10 per cent global market share in inhalation anaesthesia niche, we are yet to maximise our full potential of these products. To accelerate growth, we have some regionally important product enhancements underway for our lead inhalation anaesthetic product, Sevoflurane, and we also plan to launch Desflurane. In addition, as we continue to transition, integrate, and gain experience with the products that we acquired from Janssen and Mallinckrodt, we believe that there is potential to grow these franchises. Further, as one of the few independent pharmaceutical companies with commercial capabilities dedicated to the hospital channel, we plan on marketing products that are developed or made by partners that lack effective commercial front-ends, particularly in the US and Europe.

**You have a strong presence in countries like US and Europe. Are there any further expansion plans?**

Our products are currently sold in 110 countries, either directly or through our local partners. We currently have direct capabilities in the US as well as a number of countries in Europe and work through partners in the rest of the world. Our primary focus for expansion is to add compelling hospital pharmaceutical products to our portfolio. With respect to our in-country presence, we periodically evaluate our go-to-market strategy in each country to determine the most effective way forward. While it makes sense in some countries such as the US, UK, Italy, or Germany, to have our own commercial capabilities, in a number of other countries we are better served with a local marketing partner. Our decision to work directly in a market is based on our understanding of the market size and attractiveness, our product portfolio and pipeline for that market, the local partner ecosystem, and our ability to do business in that market.

**How do you ensure adherence to global standards/ what steps do you take to ensure compliance to US FDA rules?**

Our products are used in a challenging and unforgiving environment – i.e. operating theatres in hospitals. Providing our customers with reliable, uninterrupted, high quality supply coupled with responsive customer service, are essential differentiators in a market where our customers frequently suffer from product shortages, due to quality issues. We are able to meet these product expectations through our established network of internal manufacturing capabilities and external supply partners in the US, Europe and India. Our commitment to quality resonates through stringent global regulatory approvals that are accredited to our manufacturing network. We keep quality at the forefront of everything that we do.

We start with accountability: quality is in everyone's Key Results Area, including mine, and not just those of the quality

department. In addition to our dedicated business and site-specific quality teams, the corporate quality team has developed a number of tools and processes that are applied across Piramal pharmaceutical businesses, including Piramal Critical Care. For example, we look to learn from others. The quality team examines citations given to our competitors and when they both conduct scheduled and unscheduled internal peer audits of Piramal manufacturing sites, they look for gaps versus current or emerging expectations. Finally the Quality team reports independently from the business team, up to the Piramal Enterprises Board, ensuring that it is empowered to enable balanced decisions.

Across the company, not just limited to Piramal Critical Care, Piramal has maintained a clean slate over a long period of time. We are glad to report that in 2017, 28 regulatory agency inspections were conducted, including five US FDA audits across plant locations, including Piramal Critical Care sites, with all of the audits being cleared successfully without a single day of production stoppage.

**What trends do you see in the industry in coming year?**

As we experienced last year, our customers remain under intense pressure to manage healthcare costs and they do have alternatives given we operate in the generics segment. We expect this to continue in 2018. This drives us to constantly ensure and demonstrate that we provide value to our customers. So in addition to reliable, high quality supply and excellent service, competitive pricing is a crucial factor to increase both market share and volumes for our existing products.

Keeping these trends in mind, within the global generics market, our product portfolio is focused on generic hospital pharmaceutical products that have complexities around manufacturing, sales or distribution. In markets where it is relevant, many of our offerings are branded, including the products recently acquired from Janssen and Mallinckrodt. These attributes make for comparatively attractive niches vis-à-vis other generic products. As we look at line extensions and new product additions, we hope to replicate our track record in selecting attractive niches while meeting our customer's needs.