INTERVIEW

Pharma cos prefer to work with few strategic CDMO partners

As the CDMO industry undergoes significant consolidation, **Vivek Sharma**, CEO, Piramal Pharma Solutions (PPS) explains to **Viveka Roychowdhury** how PPS' latest acquisition of US based CDMO Ash Stevens will help position it as an integrated CDMO for oncology drugs

How does the agreement to acquire 100 per cent stake in Ash Stevens Inc, a US-based CDMO, fit into the company's business strategy?

The percentage of drugs classified as 'highly potent' with occupational exposure limits (OELs) ≤ 10µg/m3, has been progressively increasing, and is currently estimated to be around 25 per cent of the global pharmaceutical development pipeline. High Potent Active Pharmaceutical Ingredients (HPAPIs), the active ingredients that contribute towards efficacy of these drugs, make up one of the fastest growing segments of the global API market. In response to increasing customer demand for HPAPIs, we acquired US-based CDMO Ash Stevens to add HPAPI capabilities to our portfolio. The company has extensive experience in handling highly potent compounds and is seeing increased demands for its offerings.

The acquisition of Ash Stevens also fits well with Piramal's strategy to build an integrated asset platform that offers value to our partners and collaborators. North America being a key market for Piramal, this development helps to serve our customers with three local facilities including the injectable facility in Kentucky for fill finish needs, the Toronto facility for complex high value APIs, and now, Ash Stevens in Riverview for HPAPIs. This acquisition is synergistic with our global capabilities and can help fulfill client requirements as an Integrated CDMO for Oncology drugs. As an example, a collaborator working in an oncology injectable formulation, can get all their needs served at Piramal: Piramal would make the early intermediates out of India, manufacture the active (HPAPI) out of Riverview, and finally, complete the injectable drug product out of its Kentucky facility.

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How has the CDMO landscape evolved in the past few decades?

Pharma firms have always adapted to the changing market place by adopting different strategies like launching authorised generics, having a generic arm to tap the generic market, acquiring biotechs to boost the pipeline, joint ventures, co-marketing agreements and so on. Declining R&D productivity and the impact of clinical attrition have driven many pharma companies to focus on core competencies, adopt outsourcing as a strategy and rationalise their manufacturing and R&D operations. They prefer to work with few strategic CDMO partners instead of multiple suppliers to take advantage of cost and time benefits. In response to these macro trends, the CDMO industry has undergone significant consolidation in the past few years to obtain proximity to clients and their end markets through a network of global sites. Integrated service providers now offer 'end to end services' from discovery to commercial launch.

With the advent of personalised medicine, niche disease targets, and biologics, there has been a shift from large volume drugs to low volume, targeted, and potent drugs with novel delivery systems and dosage forms. To meet these needs, CDMOs are adding specific capabilities such as high potency manufacturing, continuous flow, and unique formulation services to their portfolio.

Piramal is a global leader in integrated solutions and our platform of services and global facilities allow customers to work with us across different phases of the drug life cycle for both drug substance and drug product, optimising costs and time.

As a global supplier, how do you prepare to cope with political changes like Brexit? Has this impacted business?

We regularly track both market dynamics and geopolitical trends. Piramal's network of sites across North America, Europe, and Asia allows us the flexibility to quickly adapt and address any rapid shifts in policies and trends. Specifically on Brexit, our current view is that, the impact, if any, will be non-disruptive. We are working closely with our peers, government officials,

influencers, and customers, to ensure that legislation does not impact the availability and access for life saving medicines, for patients in the UK, and the European Union. While we remain optimistic that the final decision will take all this into consideration, we have alternate plans in place for QP release in the event that those get impacted: our goal will be to ensure that our customers have business continuity and get their products on time/in full.

What is the differentiator between Piramal Pharma Solutions' portfolio and other CDMOs?

Our core values of Knowledge, Action, Care and Impact serve as our guiding principles and resonate with all our customers. These values have been shaped by our tradition and collective experience; they determine how we engage with others, what we identify with and what we value.

We have created a global network of development and manufacturing facilities located in North America, Europe and Asia that offers a multitude of services covering the entire drug life cycle, from drug discovery & development to commercial manufacturing of Active Pharmaceutical Ingredients (APIs) and Finished Dosage Forms (FDFs). This sets us apart as the only service provider with a significant presence in the East and West which enables us to leverage the cost efficiencies from the east and proximity to our customers and their end markets in the west to offer truly integrated solutions.

Irrespective of our businesses, Piramal is built around three pillars that form our 'One Piramal' foundation: Quality, Environmental Health and Safety (EHS) and Customer Centricity. From the shop floor to the executive suites, there is no compromise in these elements. These principles are highly valued by our customers in the industry that we operate in. We constantly engage with our customers to identify improvement opportunities and focus on meeting customer expectations collaboratively.

What are the business growth drivers and possible speed breakers? Would increasing quality expectations from regulators add to the cost of doing business and how is this impacting your revenues?

At Piramal, there is no trade-off between quality and being cost effective. We consider them mutually exclusive. Without quality, cost competitiveness would not matter. We at Piramal have focussed on 'Quality as a Culture', as opposed to Quality as a Compliance Tool'.

With a strong quality framework in place, Piramal seeks to be competitive by building a brand that stands out. We view Quality as our identity – something which represents our DNA. We employ the concept of "Global Vision, Local Execution" which enables each site to serve their customers at their location but with the global standard of quality upheld by Piramal. Finally, we channelise our efforts to ensure that quality is our differentiator – which attracts customers scouting for 'preferred' partners.

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