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Olon CEO Says European Systems Must Value Security Of Supply

As Italian API Giant Continues to Invest In Supply-Chain Resilience

by David Wallace

With Olon investing significantly in its production capacity and technical capabilities, CEO Paolo Tubertini believes the API specialist is well-positioned to provide resilience within the European supply chain. However, the chief executive also told *Generics Bulletin* that this robustness needs to be valued by pricing mechanisms.

Speaking with Olon CEO Paolo Tubertini, his commitment to the promise of generics is clear. Several times during the chief executive's conversation with *Generics Bulletin*, he reiterates the importance of the active pharmaceutical ingredient specialist being able to offer "quality and affordable medicine" as part of the generics industry, describing this principle as much in terms of a societal necessity as a business objective.

However, Tubertini is also clear that part of this equation is assuring a reliable supply of quality and affordable medicine – and that pricing mechanisms need to be adapted to recognise the value of a resilient supply chain, at a time when Olon is investing more than ever in ensuring that its capabilities and expertise are up to the task.

"The generic dynamic is changing continuously," Tubertini told *Generics Bulletin*. "Robustness of the supply chain is becoming mandatory in order to have success in the market." For this reason, Olon was "selecting carefully our areas of expansion, so that we can commit, where we think that we can have the opportunity to establish a resilient supply chain."

Recent investments have included expanding Olon's high-potency capabilities at its Mahad site in India (Also see "*Italy's Olon expands through Indian plant*" - Generics Bulletin, 7 Sep, 2018.), as well as investing in capacity and expertise to develop peptides at its Settimo Torinese biotech hub (*see sidebar*).

Meanwhile, a new R&D hub near the firm's headquarters in Rodano, Milan, is expected to act as a center of excellence for Olon's global network as well as providing a "springboard for future growth prospects." (Also see "*Olon Invests In R&D Hub In Italy*" - Generics Bulletin, 26 May, 2022.)

Olon Expands On Multiple Fronts

By David Wallace

29 Sep 2022
Italian API and CDMO specialist Olon is expanding its high-potency capabilities at a site in India, at the same time as unveiling plans to invest a further €30m in a domestic biotech hub.

Read the full article here

Discussing Olon's investment in recombinant peptide technology, Tubertini said "we will have the capability to produce through microbial fermentation, that means we are fully integrated into the supply chain; raw materials are widely available such as soy oil, glucose, etc., not [at risk from] a complex supply chain that can be easily disrupted."

"And in other opportunities, we are working on highly potent API, that is an area in which Olon has a longer expertise. We were one of the first, in the nineties, to produce our highly potent APIs for innovators."

Moreover, "we are also entering the ultra-high-potent APIs area, where an extremely high level of containment is needed." This latter initiative was "an new area, something that is booming for the innovator businesses, but consequentially also for the generic industry there will be the need in the near future for those kind of materials," he noted. "A lot of investments are also being done for the sustainability of the company."

Olon was investing more than ever in these projects, Tubertini suggested: "We peaked with the level of investment in 2022, and in 2023 we expect to be above the peak of 2022," he pointed out.

Not Only Focused On 'Premium' Generics Markets

Asked how Olon was positioning itself with generics industry partners specifically, Tubertini said that when the firm had recently set its new vision mission, "we clearly stated that one of the goals that we have is to improve the health of the people through technology and science, and we have to bring this value on a global perspective."

"We redefined the way we develop API for generics," he described, explaining that Olon was not only targeting "premium markets" and not just aiming to develop compounds that were cost-effective for those markets, "but we also aim to bring quality and affordable medicine on a worldwide perspective, including also in areas where lower-income populations are present."

"Each time we are able to sell our API in a less regulated market, I personally feel a success," Tubertini described, because "even if we might have a lower margin, the mandate we set is reached: quality and affordable medicine."

Questioned over whether sustainability and ESG aspects were becoming more significant for a company like Olon, the CEO replied, "we are operating under some of the strictest compliance requirements in the world, and we are continuously investing also in that area." And "generally speaking, sustainability is something in which I think all the industry needs to look into."

One of the most important topics for Olon was CO2 emissions, Tubertini suggested – "not because the others are not important," but because other aspects were largely under control. "But CO2 emissions I think are one of the biggest issues that we have to face as a society."

Pointing to the challenge of steam production, he said "there is no answer for how to produce steam levels in huge quantities without CO2 emissions. Of course, we can use biomass, but in any case, with some CO2 emissions."

This was "an open question – I do not have the answer," Tubertini said. "We are working on it to try to understand what the technologies are available, what are the solutions – because our mandate in the society for the generic business is in any case, affordable quality medicine."

Energy Cost Inflation Is a Short-Term Pressure

Discussing current inflationary pressures in energy costs, Tubertini said "there was a peak and now the prices are moving down, [but] still at a level that is much higher in comparison to what was before."

"This is an issue for competitiveness in Europe on a wider perspective," he acknowledged. "The chemical industry is a strong consumer of electricity, and this is affecting the P&L of the industry."

However, one effect of the inflation was that efficiencies were being implemented more quickly, he suggested. "In some cases, you are pushing to move as quick as you can to find energy efficient production systems. A lot of [efficiency] investments that before were not in scope, because the return on investment was too long, have been implemented… I want to see the positive side."

But he conceded that the current peak "will cause some stress in the market."

"In the generics industry, it is important to be cost effective – we will suffer for sure, we are suffering, in some cases we are forced to increase the price to the customer, in some cases also the customers are forced to increase the finished product prices."

"This is against the mandate that we have," he outlined, "because in the generic industry the target is to provide affordable medicine. This is the reason why we are in the industry."

Supply Chain Robustness Must Be Valued

Returning to the issue of supply-chain robustness more broadly, Tubertini said "the issue that I see is that the assurance of supply is an assurance that needs to be paid."

"But of course," he said, "if price is just covering the cost of goods and production costs, then that premium for the 'assurance' is not paid."

"If you look at the innovative sector," he suggested, "no one will have supply-chain disruptions." When innovators reach the market, "they have spent a tremendous amount of money for development – but the gap between the price and cost of goods is really huge."

"They have to protect that margin in order to recoup all the investment they've made in the past – this is correct," he acknowledged. "But this is not happening for generics," leading suppliers to place less value on the need to maintain certain product lines where margins may be minimal. "Something needs to be changed in [pricing] regulation in order to keep the price at a premium," he said, "to pay for that assurance."

Asked whether he could foresee procurement processes placing more value on supply-chain security, as well as changes to pricing mechanisms that might allow prices to go up – as exemplified by tentative steps taken recently in France and Germany (Also see "*France's Gemme Claims A Victory With Price-Cut Reversal*" - Generics Bulletin, 8 Feb, 2023.) (Also see "*Draft Bottleneck Bill Must Go Further, Urges German Generics Body*" - Generics Bulletin, 24 Feb, 2023.) – Tubertini said "my personal opinion is that if we want a free market, authorities in Europe need to leave the price free to move."

"It won't work if authorities just regulate the prices," he said, with many pricing and procurement decisions involving complexities that were not always apparent to those in charge of existing systems.

As an example, he suggested, an increase in the costs of producing an older generic might make it unprofitable for companies to continue supplying that product at a price that was fixed decades ago, leading to a discontinuation; but a newer generic in the same category which had a similar therapeutic effect that could be supplied at a much higher price point might continue to be sold. This would lead systems to have access only to the higher-priced treatment, rather than a more affordable alternative.

It would be “much better to increase the reimbursement price of the older compound, if the cost of managing a specific disease would still be lower,” Tubertini indicated. But “the authorities are not always looking at the global picture.”

Regulatory Data Burden Adds Additional Pressure

Moving on to discuss regulatory processes and the burden on industry, Tubertini highlighted that regulators were requiring “more and more data in order to receive approval for new compounds, for a new generic or for a change in the supply chain,” making it harder to meet the promise of supplying quality medicines at an affordable price.

This meant that, in cases where Olon might see the need for an improvement to supply-chain robustness, “you might want to make improvements – but before making the changes you need a lot of data to be produced,” adding cost and complexity.

In this way “the regulators are missing the real trade-off for the generic industry,” he suggested. “It is complicated, the level of data that you have to produce is so high that in some cases, the robustness of the supply chain is something that is not really manageable in term of cost.”

“The target is to have affordable and quality medicine,” Tubertini reiterated. “To have only quality medicine, as a mandate, does not take into account cost.”

This trade-off should be part of the regulatory authorities’ evaluation when the rules and guidelines are elaborated and approved, he suggested. “In my opinion, currently the health authorities are taking care of quality, but not enough caring about the robustness of the supply chain and cost of materials.”

Manufacturing Incentives Must Address Cost of Production

Turning to the state of the European manufacturing sector, Tubertini was asked whether enough was being done to incentivize local production, as API sourcing increasingly moves to low-cost markets such as India and China despite the supply-chain weaknesses that were exposed during the COVID-19 pandemic. (Also see "*Stampa Urges Investment In European Manufacturing*" - Generics Bulletin, 22 Mar, 2022.)

“A lot of focus has been placed on incentives to support investments in assets,” he observed. “But investments are only one part of the cost of the compound.”

“In case of commodities it is not a matter of the cost for building the plants, but also the running costs,” he pointed out. “The real reason why a specific compound might not be manufactured in Europe is the running cost of production.”

“Subsidizing the industry is something in which I don’t see a real goal,” he set out. But “what we think could be done to have more significant production in Europe, is to grant a premium price if you have a full European supply chain. If pharma companies have a premium, at least a part of the production will take place in Europe."

"If we want to have more production in Europe, perhaps we have to pay more for the material that is produced in Europe," he summarized.

However, when it came to subsidizing companies directly, he said "I don't think it will work," not least "because in any case you have to maintain the right level of competition in in the industry."

No Plans To Move Into Finished Dosage Forms

Looking ahead to the future for Olon, Tubertini concluded by highlighting the opportunities for both inorganic and organic growth that the company perceived.

"We have 11 sites, all those 11 sites have been acquired in the last 20 years," he noted. "we are specialized in API production – for the time being we have no interest in finished dosage."

"We want to continuously enlarge the offer of technology and enlarge the product portfolio, enlarge the services that we are offering to the whole industry."

"Olon is active in both the generic and innovative space," he highlighted, pointing out that the company wanted to ensure sustainable growth by balancing its interests in "all the aspects of the industry, putting together all the synergies that we can have internally in order to be able to commit to our goals for the market."

But he concluded by returning to the importance of valuing local production and supply chain security, cautioning that in Europe "the generic market in Europe is growing much faster than productions in Europe. So the difference between the offer and the demand is continuously increasing. Prices are not set in a way that allows the internal market in Europe to correct itself."