From simple to complex:

Hikma's injectables capabilities uncovered

As one of the world's largest generic pharmaceutical companies, Hikma operates in North America, the Middle East, North Africa (MENA), and Europe, with 29 manufacturing facilities, three research and development (R&D) hubs, and around 9,400 employees globally. Operating under three main business segments – injectables, branded (solid orals) and Hikma Rx (respiratory, nasal, semi-solids and liquids) – the company boasts a portfolio of over 825 products.

Hikma was founded by Samih Darwazah in 1978, and his strategy was clear from the beginning: to make medicine of uncompromised quality that meets the most stringent international standards and is accessible to patients. With a current focus on injectables, *Manufacturing Today* sits down with Natheer Masarweh, Senior Vice President, Injectables Operations, who explains more about the sector and how it continues to address unmet medical needs worldwide.

"Our work is driven by a commitment to expand access to high-quality medicine," Natheer affirms. "This responsibility shapes our values, which are built on collaboration, care, and innovation. Every employee understands the purpose behind their work and how it directly impacts patient access to essential medicine. Whether in manufacturing, R&D, supply chain or corporate functions, our people uphold this commitment every day, recognizing that quality and accessibility are fundamental to healthcare.

"We continue to invest in advanced automation to minimize human intervention – the primary source of microbial contamination. This approach

▲ Natheer Masarweh, Senior Vice President, Injectables Operations

strengthens product safety and reliability while reducing regulatory risks."

As a top three supplier of generic injectables in the US, we develop and manufacture simple and complex injectables products that actively help tackle critical medical requirements in hospitals.

A prime example is the recent launch of Tyzavan®, an FDA-approved, ready-to-infuse glycopeptide antibacterial agent designed to treat serious infections.

"Tyzavan® is a vancomycin premix with room temperature stability," Natheer explains. "Offered in prefilled bags, it enables patients to be treated more efficiently with a reduced risk of compounding errors, demonstrating how we leverage our capabilities to serve the evolving needs of healthcare professionals and their patients.

"Another key example came during the Covid pandemic when we prioritized critical-care medicines, such as respiratory drugs, analgesics, and anti-infectives. We operated at maximum capacity to meet the surging demand, and, during that time, we supplied 11 of the 13 most used intensive care unit injectables in the US.

"Importantly, we work closely with regulatory authorities to ensure essential medicines remain consistently available. By proactively monitoring potential supply disruptions and collaborating with partners, we can anticipate shortages, scale production when needed, and maintain continuity of care in a volatile market."

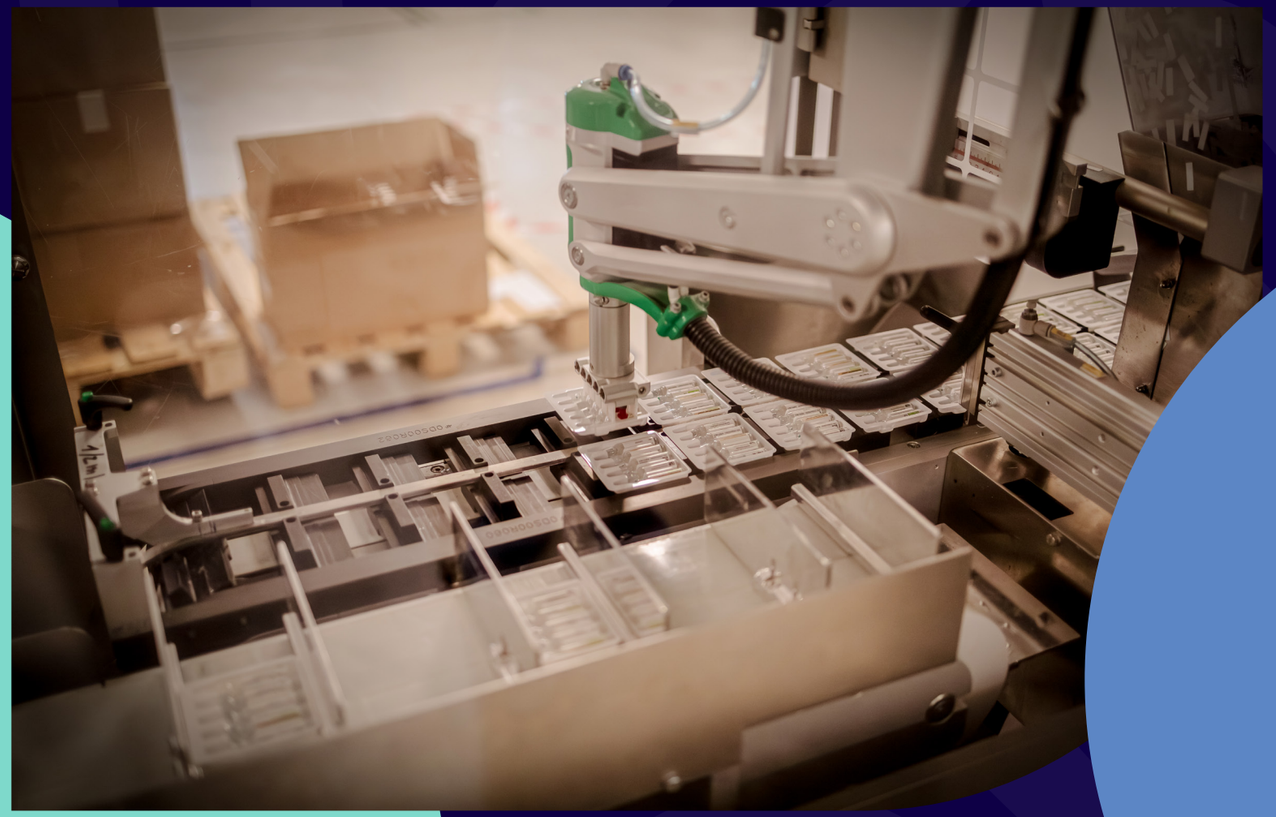
Leveraging advanced technologies strengthens efficiency, precision, and compliance within the company's production sites. By embedding automation, digital monitoring, and data-driven decision-

making into daily operations, Hikma ensures consistent quality and dependable supply. Natheer emphasizes that these capabilities are not optional: “They are fundamental to maintaining our competitive edge. Modern manufacturing allows us to scale responsibly, respond quickly to shortages, and deliver essential medicines with the reliability patients depend on.

“Digitalization also improves real-time visibility across our operations, supporting predictive maintenance and faster interventions to potential disruptions. Integrated compliance systems embedded in these technologies ensures adherence to stringent global regulatory standards, reinforcing trust with healthcare providers and regulators.”

Trust is a priority when it comes to the company’s customer service standards, as it strives to assure customers they can

expect the highest quality, proven technical expertise and robust capabilities. “At Hikma, we exceed these expectations,” Natheer continues. “Our facilities are regularly inspected by leading regulatory authorities such as the FDA, EMA, MHRA, GCC, and by ANVISA. We combine advanced manufacturing technology with rigorous quality systems for precision and consistency at every stage. This commitment not only builds trust but positions us as preferred partners for companies seeking reliability, compliance, and scalability. We work with partners who are integral in diversifying our portfolio and bringing innovative products to patients. Our broad geographical presence, strong manufacturing capabilities, and commercial team with deep market knowledge and longstanding reputation make us an attractive partner. A good example is our



recent US launch of Enoby and Xtrenbo – two denosumab biosimilars developed in partnership with Gedeon Richter. Under a licensing agreement, Gedeon Richter handles manufacturing while Hikma leads commercialization and regulatory compliance. It's a partnership built on complementary strengths, with the shared goal of getting high-quality medicine to patients faster."

Balancing portfolio expansion with technical depth and expertise is a priority for Hikma, as demand grows for more complex and specialized medicines. To achieve this, the company is looking at more complex injectables – a high value segment requiring advanced expertise and innovation, as Natheer elaborates: "Our approach involves building internal capabilities through organic development, and strategic partnerships which accelerate our progress through targeted acquisition. Our Tyzavan® launch exemplifies this strategy; our R&D team in Zagreb developed this ready-to-use formulation with room temperature stability. This achievement demonstrates our ability to integrate acquired knowledge with internal expertise to deliver innovative solutions. By focusing on complex injectables, we're expanding our portfolio while reinforcing our position as a trusted partner for advanced therapies."

Looking ahead, Hikma will continue to expand its Injectables division by increasing its manufacturing footprint across North America, Europe, and the MENA region, with a view to strengthen its supply chain, reduce lead times, mitigate logistic risks, and ensure uninterrupted access to critical medicine. "This regionalized model enhances resilience and positions us closer to patients and healthcare providers," Natheer concludes. "This reinforces Hikma's competitive advantage, allowing us to respond faster to market needs, support global health priorities and deliver sustainable growth." ■

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