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Sandoz Aims To Be 'First In And Last Out' In North America

New Regional Head Keren Haruvi Lays Out Strategy In US And Canada

by David Wallace

Sandoz is determined to be "first in and last out" on key product opportunities, while also seeking to strengthen its pipeline through deals and partnerships, the company's new North America head, Keren Haruvi, tells *Generics Bulletin* in an exclusive interview.

At the start of 2021, *Sandoz* performed a major reshuffle of its management in North America that saw regional head Carol Lynch move on to become the Novartis unit's global chief business officer. At the same time, former Novartis head of mergers and acquisitions, Keren Haruvi, took over as president of Sandoz US and head of North America for the generics giant. (Also see "*Haruvi Takes Charge Of Sandoz North America*" - Generics Bulletin, 14 Jan, 2021.)

A couple of months on from her appointment, Haruvi has talked to *Generics Bulletin* about how Sandoz is seeking to position itself as "first in" to new product markets while also aiming to be "last out" through cost competitiveness and supply stability; how the firm is planning to bolster its pipeline through business development and licensing opportunities as well as acquisitions; and how it perceives the generics and biosimilars landscapes in the US and Canada.

With the US representing Sandoz' largest commercial and country organization – accounting for more than $2.1bn of the firm's $9.6bn total turnover in 2020 (Also see "*Biosimilars Boost Offsets Generics Slide For Sandoz*" - Generics Bulletin, 27 Jan, 2021.) – Haruvi was clear on what her immediate priorities would be as the new country president and head of North America.

"As we navigate the COVID-19 pandemic, our top priority continues to be ensuring that patients

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KEREN HARUVI

can access the medicines they need, when they need them," she explained.

"To accomplish this, I am focused on increasing our current portfolio of generic injectables, biosimilars, oral solids, dermatology, ophthalmic, respiratory and other specialty medicines through internal and external investments; supporting policies that improve patient access to high-quality, more affordable biosimilar medicines; and enhancing supply chain reliability and data and digital for further efficiencies."

"We also hope to drive performance in our inline product portfolio, which is in a very competitive market."

> ***"Our biggest challenge in the short-to-medium term is strengthening our pipeline, so we will focus on BD&L opportunities and bolt-on M&A, and explore strategic partnerships across the value chain."***

Asked how her experiences as global head of M&A for Novartis would feed into her new role, Haruvi said that "throughout my 17-year career in healthcare, I've helped companies develop and implement strategies for sustainable growth, and this will be a priority at Sandoz as well."

"In North America," she observed, "our biggest challenge in the short-to-medium term is strengthening our pipeline, so we will focus on business development and licensing opportunities and bolt-on M&A, and explore strategic partnerships across the value chain, to strengthen our portfolio and accelerate our growth."

Questioned over the previously planned billion-dollar divestment of Sandoz' generic oral solids and dermatology businesses to Aurobindo – which was called off nearly a year ago (Also see "*Sandoz And Aurobindo Cancel US Deal*" - Generics Bulletin, 2 Apr, 2020.) – and how that development had affected the firm's strategy, Haruvi insisted that "we remain committed to the generic oral solids and dermatology segments and our efforts to identify opportunities to

stabilize and then grow this business."

"Our strategy is based on a commitment to lead the market across key products and geographies, driven by a true generic mindset culture," she said, echoing recent comments made by Sandoz CEO Richard Saynor on the firm's "pure play" approach to generics and biosimilars. (Also see "*Sandoz' Saynor Insists On Value Of 'Pure Play' Approach*" - Generics Bulletin, 28 Jan, 2021.)

"What this means," Haruvi elaborated, "is that we will be focused on performance, being proactive versus reactive to the changing dynamics in the market, and we will work to simplify our way of working."

"Sandoz' global strategy is to focus on its core generic and biosimilar business, with the ambition to be the world's leading and most valued generics company," she insisted. "We have set our sights for Sandoz North America to achieve the leading position amongst all generics companies by 2026."

'First In And Last Out'

Under the leadership of Saynor, Haruvi elaborated, Sandoz' divisional strategy had been refined to focus on three key areas: developing a "broad and consistent" pipeline of off-patent launches across major geographies and therapeutic areas; positioning Sandoz to be "first in, by having a strong pipeline with a concentration on being first to market, and to be last out by way of competitive costs and stable supply"; and instilling the "true generic mindset."

In North America, she said, "we are realizing this strategy with a focused approach to grow segments in the US market, including injectables, biosimilars, oral solids, dermatology, ophthalmic, respiratory, and other speciality medicines."

Pressed on whether respiratory products were still a key category for the company following its decision to cease development of a planned Advair (fluticasone/salmeterol) generic (Also see "*Sandoz Will Not Pursue US Advair Rival*" - Generics Bulletin, 30 Jan, 2020.), Haruvi was clear that "yes, in the US, respiratory products continue to be an area of focus and investment for Sandoz to support our long-term growth."

Meanwhile in Canada, she noted, "Sandoz has one of the largest hospital portfolios of injectables and generics market share, which we will continue to build on to strengthen our position as a trusted partner to pharmacies, hospitals, physicians, governments, and payers."

> *"As we prepare for a post-COVID world, all savings options should be on the table, and generic and biosimilar medicines stand out as a method of creating sustainability and improving patient care."*

In the context of the coronavirus pandemic, "the role of generics and biosimilars in delivering savings is today more important than ever," Haruvi insisted, with estimated US financial losses from the COVID-19 pandemic running into the hundreds of billions "and projected to steadily increase as the impacts of the pandemic are realized."

The pandemic "has put enormous pressure on the entire healthcare ecosystem, and the pharmaceutical supply chain," she acknowledged, "with hospitals, health systems, and providers leveraging every resource available to treat COVID-19 and secondary infections."

"For many companies like Sandoz," she described, "this has resulted in an increased demand from patients and governments for key medicines, including antibiotics – where Sandoz is a world leader – and antivirals, injectables, and other critical medicines."

Responding to these challenges, she pointed out, Sandoz had "expanded its manufacturing capacity to maintain a stable supply of generic medicines for patients, while also delivering on a number of additional commitments to contribute to the global COVID-19 response." (Also see "*Sandoz Pledges Price Stability Amid Coronavirus*" - Generics Bulletin, 27 Feb, 2020.)

"As an industry," Haruvi declared, "we have a responsibility both to plan for business continuity in times of change and to ensure the same global quality standards regardless of where our products are made, or by whom. We've taken the challenges presented by COVID-19 as an opportunity to improve efficiencies by accelerating digitization, and introducing new, more flexible ways of working."

"As we prepare for a post-COVID world," she said, "all savings options should be on the table, and generic and biosimilar medicines stand out as a method of creating sustainability and improving patient care." And "in the coming years, there will be opportunities to drive preference for generics and biosimilars and we are focused on ensuring that we can actualize in those moments."

'More To Be Done' In US Generics

Asked whether there were any major changes foreseen to Sandoz' operating model and strategy in the US and Canada, Haruvi said the company was "constantly examining opportunities to

improve efficiencies and deliver impact for patients and customers."

Pointing to the firm's US collaborations with Civica Rx and Kit Check, she said these initiatives were allowing Sandoz "to ensure supply of critical medicines remains consistent for optimal patient care." (Also see "*Sandoz And Civica Rx Strike Five-Year Deal*" - Generics Bulletin, 9 Jul, 2020.) (Also see "*Sandoz US Rolls Out RFID-Tagged Injectables*" - Generics Bulletin, 6 Oct, 2020.)

"Agreements like these enable Sandoz to deliver on our purpose to pioneer access for patients," she summarized. "As we work towards a post-COVID world, flexibility and agility across all healthcare sectors, including the Sandoz go-to-market model, will be critical for success."

And commenting on the general state of the US generics market, Haruvi acknowledged that despite healthy penetration rates that were allowing savings of as much as $313bn from generics in 2019 alone (Also see "*US Saves $313bn From Generics And $2.2bn From Biosimilars*" - Generics Bulletin, 6 Oct, 2020.), there was still "more to be done to ensure generic manufacturers can bring new therapies to market in a timely manner."

"We will continue to work with the US Food and Drug Administration to ensure that regulations and guidance documents provide a clear pathway for the development and approval of complex generic dosage forms," she pledged.

Haruvi also discussed the recent decision by the US Court of Appeals for the Federal Circuit to re-examine a controversial decision over induced infringement by generics that carve out patented indications from their labels, which had been criticized by Sandoz CEO Saynor as blocking a "routine route to market" for generics. (Also see "*Sandoz Keeps Tabs On Teva Skinny Label Ruling*" - Generics Bulletin, 28 Oct, 2020.)

Confirming that the company had been "pleased with the US federal appeals court's decision to rehear *GSK v Teva*," she warned that "the panel's previous decision threatened to upend a longstanding framework that supported generic competition *and* brand innovation." (Also see "*US Court Offers Second Chance On GSK-Teva 'Skinny Label' Ruling*" - Generics Bulletin, 10 Feb, 2021.)

"Skinny labelling plays an indispensable role in accelerating the availability of high-quality, lower cost generic medicines for patients," she insisted. "Sandoz firmly believes that generic manufacturers should be able to be able to continue to use skinny labels as Congress intended, and we hope the court's decision will reflect that."

US Biosimilars Remain Constrained By Challenges

Turning to biosimilars – a "key focus" for Sandoz in North America – Haruvi observed that "while biosimilars are gaining momentum in the US, particularly in oncology, the market

continues to be challenged by a lack of payment policy incentives to drive biosimilar adoption, insufficient education and the existence of misinformation campaigns, and uncertainties created by US-specific policies for biologics naming and interchangeability."

"These barriers have a significant cost for manufacturers, as well as impact for patients and the healthcare system," she cautioned.

"Based on the most recent prices for the nine biologic drug classes with FDA-approved biosimilars, as of December 2020, estimated patient out-of-pocket lost savings is greater than $282m and increasing day by day," she suggested. "Similarly, between 2018 and 2020 the estimated year-to-date lost savings to the healthcare system is greater than $24bn."

And on the concept of interchangeability – which still remains something of an unknown factor in the US biosimilars arena – she pointed out that "in terms of costs, companies wishing to pursue an FDA designation of interchangeability would need to add tens of millions of dollars of US-specific development costs, according to the current guidance requirements."

One specific biosimilar product that has been a major focus of Sandoz' energies in the US is its FDA-approved Erelzi (etanercept-szzs) rival to Amgen's Enbrel, with the two firms having been embroiled in long-running litigation that has seen key patents upheld at the appeals court level, thus keeping Sandoz' version off the market. (Also see "*Nine More Years? Sandoz Loses Again On Enbrel Biosimilar*" - Generics Bulletin, 2 Jul, 2020.)

Referring to the firm's recent petition to the US Supreme Court to review the appeals court's decision (Also see "*Sandoz Takes Enbrel Fight To The US Supreme Court*" - Generics Bulletin, 9 Feb, 2021.), Haruvi maintained that "we believe that valid intellectual property should be respected. However, in this case, we believe the patents are invalid and that Amgen should not be able to use them to extend the drug's exclusivity in the US until 2029."

"Sandoz remains deeply committed to make Erelzi available to US patients with autoimmune and inflammatory diseases as soon as possible," she insisted. "Erelzi was approved by the FDA in 2016, yet US patients continue to wait. Estimates suggest that a biosimilar etanercept could save the US healthcare system up to $1bn per year."

Canadian Biosimilars Slow To Build

Meanwhile, in Canada – where Haruvi noted the firm had "just launched our fifth biosimilar" in the form of its Hyrimoz (adalimumab) rival to Humira (Also see "*Sandoz Confirms Launch Of Humira Rival In Canada*" - Generics Bulletin, 16 Feb, 2021.) – she observed that the market was still behaving somewhat sluggishly.

"In Canada, the pharmaceutical market represents a total of 762 million prescriptions, including

13 million (1.7%) biologics prescriptions," she described. And "out of all biologics prescriptions, just 4.3% (559,000) represent biosimilars."

"While some provinces have led the way and implemented biosimilar switching policies for safe and effective transition of patients currently receiving biologics, a large proportion of the country is still not embarking on the same route," she lamented. (Also see "*Alberta Is Second Canadian Province To Switch To Biosimilars*" - Generics Bulletin, 16 Dec, 2019.)

"Strategies undertaken by manufacturers of originator biologics still limit the uptake of biosimilars," Haruvi explained. "Lack of regulations and the presence of strong originator funded patient support programs are the main barriers."

But "in spite of this, we remain very confident that more provinces will implement biosimilar switch policies in 2021 and we expect the biosimilar market in Canada to double this year, reaching $1bn," she outlined, reiterating that "the launch of the our most recent biosimilar, Hyrimoz, as well as the expansion of biosimilar switch policies, will be important growth drivers in 2021."

Localization Not The Sole Answer To Supply Chain Disruption

Haruvi was also asked about recent trends seen in various regions, including the US, to pursue policies aimed at bolstering local manufacturing and domestic production of essential medicines, in the aftermath of supply disruptions seen in the wake of the COVID-19 pandemic. (Also see "*Pandemic Perspectives: Cracks In Global Supply Chain Lead To Localization Trend*" - Generics Bulletin, 15 Mar, 2021.)

"For any manufacturer, diversifying supply and ensuring there is no single point of failure is key to supporting a resilient and agile supply chain," she insisted. "If an entire pharmaceutical supply chain is dependent upon one geographic area, a regional disaster or trade restrictions to or from that area could lead to significant infrastructure and supply disruptions with global implications."

But Haruvi also pointed out that "onshoring production is only as strong as its weakest link. As it would be unfeasible to source all components and chemical starting materials in the US, onshoring does not fully address all aspects of supply chain risk."

"While recent domestic manufacturing initiatives are understandable," she said, "we need to ensure that any move in response to these proposals, such as repatriating manufacturing of drug products or active pharmaceutical ingredients, make sound long-term economic sense and do not weaken our ability to reliably supply needed medicines."

"For example, throughout the COVID-19 pandemic Sandoz has managed to ensure a dependable

supply of medicines through swift action to increase production in the face of rapidly surging demand," she noted. "We were able to meet this demand, in part, because of our global footprint."

"Moving forward, we are focused in three primary areas that we believe will have the greatest impact on strengthening our supply chain: increasing the digital visibility we have with our suppliers and customers to see and respond to risk earlier; continuing to establish sound inventory buffers and alternate supply sources; and continuing to source from countries that have demonstrated strong trade and regulatory track records with ensuring strong, resilient supply."

Pursuing An 'Inclusive, Diverse' Culture

Finally, Haruvi highlighted that another of her "near- and long-term" priorities in her new role would be "growing an inclusive, diverse and entrepreneurial culture at Sandoz."

This, she said, would form "a core component of our strategy to emerge from the pandemic stronger and with an enhanced understanding of the needs of the diverse communities we serve."

"I strongly believe that culture and diversity drive performance," Haruvi outlined, adding that she had been "delighted by our recognition this year as a Top Employer by the Top Employers institute."

"True change starts from within, and I'm committed to supporting a culture at Sandoz that can drive change across the industry, helping us better understand the needs of the diverse patient populations that rely on Sandoz to provide the medicines they need when they need them."