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Phlow Seeks To Build On Fresenius Kabi Collaboration

Significant Potential To Continue To Collaborate, Insists Phlow's Chief Business Officer

by Akriti Seth

US-based Phlow and Fresenius Kabi have announced an alliance to supply essential medicines, including injectables, for public health emergencies and to Children's Hospital Coalition, a project by Phlow. In an exclusive interview with *Generics Bulletin*, Phlow chief business officer Dan Hackman talks about the partnership, addressing US supply chain disruptions, domestic manufacturing and more.

Phlow and *Fresenius Kabi AG* have announced an alliance that will see the firms collaborate to supply essential medicines, categorized as priority medicines by the US Food and Drug Administration. "We're extremely excited about the collaboration with Fresenius Kabi," said Dan Hackman, chief business officer of Phlow, as he discussed the deal in an exclusive interview with *Generics Bulletin*.

"Fresenius Kabi, like Phlow, is committed to a fully US-based integrated supply chain," said Hackman. "We have an opportunity. Once we start producing our active pharmaceutical ingredients, Fresenius Kabi will qualify those API and integrate them into their finished dosage products. The alliance is going to allow both companies to serve a lot of patients and create a lot of value."

Commenting on the partnership, Eric Edwards, president and CEO of Phlow said the firm was "thrilled to enter into a broad strategic alliance with Fresenius Kabi for this critical work of reliably supplying high-quality US-based essential medicines."

In a recent interview with Generics Bulletin, Edwards had revealed that the company - which

benefited from an award of hundreds of millions of dollars in federal government funding in the early stages of the COVID-19 pandemic (Also see "*US Plows \$354m Into Phlow*" - Generics Bulletin, 20 May, 2020.) – was currently "in the final stages of negotiating contracts with very significant and large, global generic manufacturing companies, which provides another level of commercial validation for Phlow's products" *(see sidebar)*.

Furthermore, Phlow and Fresenius Kabi have also agreed to partner to make essential medicines rapidly available in the event of a public health emergency by being prepared to rapidly convert APIs stored in Phlow's Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) into finished drug products.

Phlow CEO Reveals Possible Partnerships With 'Global Generics Manufacturing Companies'

By Akriti Seth

03 Sep 2021

In the second part of an exclusive interview with *Generics Bulletin*, Phlow CEO Eric Edwards has revealed that the company is at the precipice of entering into agreements to co-develop essential medicines in the US. Edwards has also recognized the Biden administration's efforts to secure domestic supply, offering suggestions on how to fix "America's broken supply chain."

Read the full article here

John Ducker, president and CEO of Fresenius Kabi USA, said "our collaboration with Phlow will further advance our efforts to make essential injectable medicines more accessible to more US patients." He added, "Fresenius Kabi has built one of the largest sterile injectable manufacturing networks in America, and we will more than double our capacity in the next few years to support America's efforts to strengthen its domestic pharmaceutical supply chain."

"This alliance is designed to help resolve drug shortages and ensure that Americans have an uninterrupted supply of critical essential medicines at all times, including in the event of a crisis such as a future pandemic, natural disaster, or trade dispute when our domestic supply chain is most vulnerable," insisted Phlow.

"We think that there's significant potential for both companies to continue to collaborate"

According to the agreement, both companies will work together to supply private-label products

specifically for hospitals that are part of Phlow's project – the Children's Hospital Coalition – and will also co-develop and manufacture novel pharmaceutical products.

Hackman said "the partnership accelerates our ability to deliver a product to the Children's Hospital Coalition that we formed with more than 10 of the leading children's hospitals about six months ago." He continued, "it helps us build out our rapid conversion network for our API programme with the US government."

The companies noted that the children's hospitals often must prepare their own medicines, which includes reformulating adult doses to meet the unique needs of children.

"If certain adult medicines are in short supply during a public health crisis, children's hospitals may struggle to access needed medicines, forcing patients onto alternative therapies or delaying needed treatments," the partnering companies said. "Fresenius Kabi and Phlow intend to address this need by producing a reliable supply of ready-to-administer medicines in dosage forms appropriate for children."

Talking about supplying medicines to the Children's Hospital Coalition, Edwards emphasized that "at Phlow, we are dedicated to advancing essential medicine solutions to ensure that no patient, especially a child, ever has to be told that a critical medicine is unavailable because of a drug shortage or other supply chain disruption."

Expanding Collaboration With Fresenius Kabi

Asked if Phlow's collaboration with Fresenius Kabi would further expand in future, Hackman said, "yes, I think it will." Calling it a "broad-based, multi-faceted strategic relationship" Hackman said, "we think that there's significant potential for both companies to continue to collaborate."

"The teams are already hard at work to advance the multiple work streams and look forward to making as much positive difference as we can for patients," said Hackman.

Talking about the attraction of Fresenius Kabi as a partner, Hackman said "they're obviously a global leader in health care and clear global leader in sterile injectable manufacturing." He added, "They're aligned with our mission to have a fully integrated US-based supply chain for essential medicines and they very much share Phlow's mission to serve our most vulnerable population – the children that are treated in children's hospitals."

Commenting on Phlow's future partnerships, Hackman indicated that "we have a very, very active business development funnel." He continued, "We are working really hard to continue to strike alliances with other mission aligned companies that have the capabilities that when we add them together with Phlow's can allow us to go further and faster."

Meanwhile, Ducker said, "Fresenius Kabi's expertise in developing, filling, and finishing injected and infused medicines, combined with Phlow's support for the domestic production of APIs, provides the type of powerful solution needed to strengthen America's supply chain of care."

Sets Out Company's Pipeline Focus

Talking about Phlow's pipeline, Hackman said "the primary focus is on sterile injectable, generic medicines to start." He continued, "then from a dosage standpoint, the API that we're developing can be almost always relatively easily converted into other dosage forms, like oral solid dose."

Asked about Phlow's area of focus, Hackman said "essential medicines is a broad category that includes critical care medicines, medicines in ICU, pain management, blood pressure control, sedation. We are currently either actively working on programs or preparing our pipeline drugs in all of those categories."

Hackman added, "We also think rare disease and antibiotics are very interesting areas that also, from time to time, suffer from shortages."

"We have a disciplined process to develop the pipeline and make sure we're executing on our base programs," said Hackman, "but we see ourselves growing and expanding over time into multiple categories."

Addressing US Supply Chain Disruptions

Talking about addressing supply chain disruptions for essential medicines, Hackman said "we started on this mission to address pharmaceutical, especially essential medicines, supply chain shortages back before COVID-19. The pandemic exacerbated the problem and brought the issue to the forefront."

"The problem has gotten worse and more acute," observed Hackman. "Over the last several months, all of the supply chain issues that are in the media, it's starting to look like it's going to have a significant impact on Christmas. Those supply chain issues are hitting every sector, including pharmaceuticals."

Asked about what Phlow is doing to control supply chain issues, Hackman said, "we are laser focused, working with the government and other stakeholders to do everything we can to try to bring more solutions and immediate solutions to this very, very complex and vexing problem."

He continued, "We're fully committed with our base program of developing API through advanced chemistry and manufacturing processes and then storing them in the SAPIR, and then setting up a rapid conversion network to respond to public health emergencies."

Domestic Manufacturing, PREPARE Act And Biden Administration's Efforts

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When asked about initiatives around bolstering domestic manufacturing, Hackman said, "I think there are critical industries that for public health, and/or national defence reasons, really need to be onshore in the US."

"We need domestic manufacturing for key essential medicines in case of supply chain disruptions in the future," Edwards said in an exclusive interview with *Generics Bulletin*, as he questioned the resilience of the American supply chain in the event of a pandemic more severe than COVID-19 (*see sidebar*).

Hackman said, "This, as an industry, for both public health and national defence reasons, needs to be significantly reassured in the US. And that needs to be done in an innovative, advanced way so that we don't repeat the same mistakes and have the same market failures that have happened over the last 20 or 30 years."

'Critical To Bring Back Domestic Manufacturing Of Key Essentials' Insists Phlow CEO

By Akriti Seth

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In an exclusive interview with *Generics Bulletin*, Phlow Corp CEO Eric Edwards has criticized the growing list of drug shortages in the US. He outlined the government-backed company's objective of tackling drug shortages and supply chain vulnerabilities, to create a national stockpile of essential medicines.

Read the full article here

"So, bring back the essential parts of the

supply chain for essential medicines and other critical medicines, and do it in a highly innovative entrepreneurial way," insisted Hackman.

Commenting on the recently introduced bipartisan legislation to create an emergency supply of APIs used in vital generics and to incentivize domestic manufacturing of these ingredients under the banner of the Promoting Readiness and Ensuring Proper Active Pharmaceutical Ingredient Reserves of Essential Medicines Act, Hackman said, "We are extraordinarily excited about the PREPARE Act and are working very hard to support it. We think this model is highly effective and will be highly efficient." (Also see "*US Bill Would Create Emergency API Stockpile*" - Generics Bulletin, 14 Oct, 2021.)

"We are extraordinarily excited about the PREPARE Act and are working very hard to support it"

According to Hackman, the PREPARE Act could save taxpayers a significant amount of money, compared to the way the current system works. "We think that the PREPARE Act is a great step forward and we're also supporting the administration's other efforts to shore up the US-based supply chain for critical medicines," he said.

Furthermore, Hackman said that "the Biden administration is doing a lot and they have been significantly focused on reshoring."

"We think the US government's role in investing in igniting entrepreneurs through publicprivate partnerships is really the most effective way to solve these very complex problems," said Hackman. "Igniting entrepreneurs like Phlow and others to bring innovation, advanced science, advanced chemistry, advanced manufacturing techniques to this problem is the way that the Biden administration and the US government can help solve these problems and be prepared for the next crisis."

Production Of Finished Dosage Forms

Talking about the firm's plans for the production of finished dosage forms, Hackman said, "we're working to build out that plan and for confidentiality, national security reasons probably can't say too much right now."

"But," he said, "I would just reiterate the idea of storing API and being able to rapidly convert that API through a network of fill-finish experts like Fresenius Kabi into finished dosage product on relatively short notice in the event of a crisis is highly attractive, because it's very efficient."

"We'll save the taxpayers a significant amount of money," insisted Hackney. "It is very flexible, and so can produce the dosage forms and the volumes that are necessary to meet the crisis."