Re-shoring pharma and medtech manufacturing: playing the long game

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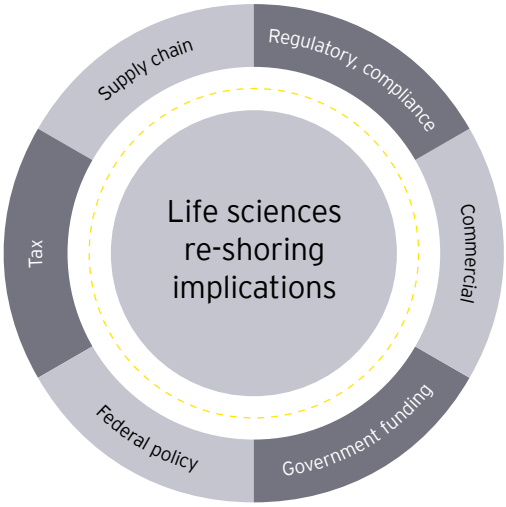
As the pharma supply chain faces an expected overhaul, there are actions life sciences executives can take now to prepare.

In brief

- Governments are leaning toward re-shoring of strategic manufacturing capabilities for business continuity
- Life sciences executives are looking to understand the capital and time needed to re-shore manufacturing
- Pharma companies are considering the need to build in redundancies or second supply channels and plan scenario actions in the case of a disruption



The pandemic has highlighted vulnerability in the pharma supply chain and the associated risks to national security and business continuity.

Even prior to the pandemic, there was a push to make the US less dependent on active pharmaceutical ingredients (APIs) and drugs manufactured overseas. So, the pandemic exacerbated the push to manufacturing medicines and medical technology products in the US. According to the US Food and Drug Administration (FDA) 2019 Drug Shortages Report, 88% of the manufacturing sites making APIs and 63% of finished dosage forms manufacturing is located outside of the US. Re-shoring this pharmaceutical manufacturing capacity will likely have major business consequences on life sciences companies.

Re-shoring the supply chain may have a material impact across the full range of the enterprise on life sciences companies with capital intensive investment in new or retooled facilities and the domino effect on tax, pricing and compliance as well as regulatory approvals.

The recent EY webcast, Re-shoring pharma and medtech manufacturing: playing the long game, hosted by Arda Ural, EY Americas Industry Markets Leader, Health Sciences and Wellness, featured EY leaders with experience in federal policy, supply chain, tax strategies, pricing and contracting, and business model innovation and transformation. They discussed the wide-ranging business implications associated with the increasing trend by the US government to re-shore. While such a move could reverse years of actions taken by life sciences companies to create a lower-cost, tax-efficient global supply chain, there may also be opportunities for companies to receive funding from the federal government to re-shore manufacturing of essential medications.

Policy implications

In August 2020, US President Donald Trump issued an executive order aimed at increasing production of essential medications and medical equipment in the US. Heather Meade, Health Policy Leader, Washington Council Ernst & Young, noted during the webcast that both Republican and Democratic policymakers are interested in the issue and it is not likely to disappear as an issue after the November election regardless of the outcome of the elections.

The executive order applies to essential medicines and medical equipment as determined by the U.S. FDA and it directs federal agencies to "buy American," except in certain cases. Meeting the requirements of the directive would likely involve many US life sciences companies reconfiguring their supply chains to take advantage of the promise of guaranteed pricing and sales volume.

"The order also requires the government to identify supply chain and security risks, which could put public pressure on companies to defend their sourcing and supply chain decisions," Meade said.

Life sciences executives will be watching the development of the regulations and guidance closely, now and post-election.

Timing and costs of re-shoring

"Re-shoring can take several years as companies need to reconfigure manufacturing supply networks and then generate the testing and data to receive government clearance," said Derron Stark, Managing Director, EY-Parthenon.

"Building new API facilities could require significant capital expenditure (CapEx) investments ranging from US$300m–US$1.5b per facility. At the same time, EY professionals estimate the cost of upgrading existing finished goods manufacturing sites could require up to $100m, while the cost to build new facilities with advanced manufacturing capabilities could reach $1b per site. Even if the manufacturing is moved onshore, many of the upstream raw materials come from Asia, creating another potential barrier to supply chain security," Stark said.

Steps that could help make re-shoring financially viable for companies include:

- Tax incentives and subsidies to offset higher fixed and variable costs
- Volume guarantees to support asset utilization
- Price commitments to support revenue in line with costs
- Regulatory streamlining to expedite domestic production
- Strategic partnerships with contract manufacturing organizations to leverage their scale, expertise and infrastructure

"Also, while the capital and timing barriers are not as high for personal protective equipment, because of the nature of the distribution system, there may need to be incentives or price supports to attract new domestic manufacturers and ensure distributors are maintaining active on-shore suppliers," Stark added.

Life sciences supply chain executives may need to take a holistic view of the supply chain and take steps to ensure that it is resilient and cost-effective even as more manufacturing moves to the US.

Tax considerations

"On-shoring could trigger a host of intertwined tax implications for life sciences companies as most have developed complex tax-optimized supply chains that involve foreign principal operating companies," said Ana Maria Romero, Principal, International Tax and Transactions Services.

Among the considerations are the potential increases in a company's tax rates if manufacturing profits are taxed at the full US tax rate and potential tax exit costs for migration of manufacturing activities.

Tax provisions that may need to be considered are the interplay of:

- Subpart F, global intangible low-taxed income (GILTI) and local country tax consequences related to exit, including tax incentive clawbacks
- Impact of potential exit taxes on company's foreign tax credit (FTC) position
- Potential benefit of foreign-derived intangible income (FDII) deduction for products manufactured in the US and exported abroad
- Impact to transfer pricing paradigms allocating profits across the value chain

"A lot of these decisions require detailed modeling from a scenario perspective to see what the [tax] impact will be for the company," Romero said.

Tax executives in life sciences companies should be aware and work closely with supply chain and commercial teams to effectively assess the tax implications of these massive reconfigurations.

Risk and resiliency

"There are several risks that need to be considered when re-shoring the supply chain, including the fact that not all raw materials are available in the US," said Alex Jung, Principal, EY-Parthenon.

Among the risks:

- APIs are compounds that are extracted from plants or minerals which are mined from the earth and may not be naturally available in the US. Even inactive ingredients may not be abundantly available
- Formulated products are typically manufactured in a geographic region near the end market, though it is not uncommon for bulk products and even some fully finished and packaged products to be manufactured in other countries and imported to the US
- Some packaging and labeling raw materials, such as rubber stoppers, plastic vials and paper labels are manufactured outside the US
- Shipping is usually done by truck and boat; companies experienced delivery risks due to local transportation shutdowns and when truck drivers contracted COVID-19
- Geopolitical risks, including trade disputes or a decision by a government to halt shipments to the US in order to preserve ingredients for their own countries
- A natural disaster, such as a hurricane, can also disrupt the supply chain

Costs can also be an issue. "You need to keep prices at pennies per pill or else it gets too expensive for customers," Jung said.

Companies may need to consider whether to build in redundancies, or a second supply channel and plan scenarios actions in the case of a disruption.

Government funding

"The sizeable costs of re-shoring will likely require government financial assistance or some form of public-private partnerships in order to be economically sustainable in the long term. The global pandemic has highlighted national security and public safety concerns related to unanticipated supply shortages in essential medicines, equipment and personal protective equipment. As a result, the Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent policy changes have refocused funding across several government sources to encourage re-shoring," said Michael Botos, Innovation and Transformation Principal.

The Biomedical Advanced Research and Development Authority (BARDA), a group within the U.S. Department of Health and Human Services (HHS), has become the coordinating force for allocating federal government funding during COVID-19. To date, BARDA has awarded US$14b of US$17.6b under its control from the CARES Act, Operation Warp Speed, Department of Defense (DOD) and other programs. While BARDA's recent focus has been on COVID-19 vaccine development, future funding and incentives will seek to encourage expansion of US domestic manufacturing to ensure supply for the Strategic National Stockpile.

What life sciences companies can consider now

In terms of the long game for pharma and med device manufacturing, we expect the global supply chain is likely to face an overhaul over the next several years. EY professionals advise the leaders of life sciences companies to prepare for potential scenarios in the near-term. The impact might be too big to ignore. To enhance future supply chains, pharma executives should ask these key questions:

- What is our US domestic manufacturing "revenue at risk" and competitive "exposure" across the product portfolio in the next 5–10 years?
- What new business model growth opportunities do we have to leverage our existing domestic manufacturing and distribution footprint?
- Have we mapped our global supply chain risk factors for products on the HHS-identified list of Essential Medicines and Medical Countermeasures (MCMs)?
- What new capabilities, processes, technologies or assets are required? Should we build, buy or partner and at what cost and timing?
- What is the downstream tax impact of any supply chain reconfiguration decision?
- COVID-19 shined a light on the fragility of our global pharma and medical device supply chain. To mitigate these risks, leading organizations may want to rethink their global supply chain of the future. The potential impact is likely too big to ignore.

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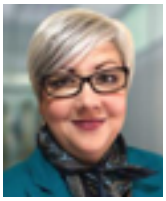

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