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USP Exec On Onshoring, Impact Of War-Fueled Metals Turbulence On Pharma

by Anju Ghangurde

US Pharmacopeia senior director, regional program operations, South Asia, Matruprasad Priyadarshi, discusses with *Scrip* the need to assess onshoring on a medicine-by-medicine basis and the organization's efforts to support quality assessments for new mRNA-based therapies. The executive also flags up new trouble spots as metals such as aluminium and nickel, used in medical products and currently witnessing price surges, are mined in the war-torn Russia-Ukraine region.

Just as pandemic-related supply chain turbulence appeared to be settling, the Russia-Ukraine conflict has thrown up new challenges, with experts now also drawing attention to the possible commodities-related impact on medical products.

In an interview with *Scrip*, Matruprasad Priyadarshi, senior director, regional program operations, US Pharmacopeia (USP) South Asia, indicated that while less than 1% of the drug product and active ingredient facilities registered with the US Food and Drug Administration are located in Ukraine, Belarus or Russia, shipping delays that began with COVID-19 have been exacerbated by the Ukraine crisis and many imported pharmaceuticals enter the US by sea. (Also see "[Reshoring Debate Continues As COVID-19 Drives New Wave Of US Drug Shortages](#)" - Pink Sheet, 7 Jan, 2022.)

"The need for onshoring will need to be assessed on a medicine-by-medicine basis. Some medicines are only made in a few locations, making them particularly vulnerable to geopolitical shocks. These medicines might benefit from a diversification of manufacturing locations, including through onshoring," Priyadarshi said.

The logistics storm building up as a result of the lockdown in Shanghai in China is only expected to further stress-test global supply chains. Shanghai Port, the world's busiest port, is said to have



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kept things going via a “closed loop bubble”, though there have been reports of trucking delays and shuttered warehouses. The Shanghai International Port Group, however, was reported by media group Caixin earlier this month as saying that the average wait time for container ships to dock at the port has been under 24 hours. (Also see "[Supply Chain Crunch Meets Olympics Shutdown: China, India Drug Makers Embrace For Perfect Storm](#)" - Scrip, 3 Dec, 2021.) (Also see "[Russia Sanctions, China Lockdown To Pinch Globally With Higher Freight, API Costs](#)" - Scrip, 6 Apr, 2022.) (Also see "[China Biotechs See Manufacturing Disruption As Cases Hit Suzhou](#)" - Scrip, 14 Apr, 2022.)

Long Term Market Impacts

USP's Priyadarshi also referred to certain “longer-term market impacts” since raw materials used in many medical products such as nickel, chromium, aluminium and silicon are mined in the conflict-impacted regions.

Prices of metals like aluminum have jumped well past the surge seen during the 2008 global financial crisis, while nickel went “crazy” against the backdrop of the Russian aggression as one media group put it, sending industry segments like electric vehicle (EVs) manufacturers scurrying for cover as prices climbed. Nickel is a key raw material for rechargeable batteries used in EVs and is also used to produce stainless steel.

Investment information and credit rating agency ICRA last month noted that global aluminium prices rose by about 18% as of 10 March compared to end-January 2022, fueled by rising geopolitical risks amid the Russia-Ukraine war. Aluminium prices touched an all-time high of \$3875/ton in the first week of March this year.

The agency's note on the global primary aluminium industry, referred to the “tight demand-supply balance” and, therefore, a low inventory level of aluminium worldwide. “Any sanction on Russian aluminium exports will aggravate the metal availability in the rest of the world, keeping prices at a high level till normalcy is restored,” ICRA said at the time.

In addition, disruption in alumina supplies from Ukraine, faced by the leading Russian producer RUSAL, and aluminium capacity cuts effected by Chinese authorities in CY2021 are expected to keep supplies constrained,

How does USP expect to help ensure common

and hence prices elevated in the near term, ICRA added. Russia contributes almost 12% to global trade in aluminium with exports primarily diverted to Europe.

While the impact of supply and price movements of key metals may perhaps not be as dramatic in pharma as in some other sectors, there nevertheless could be significant cost implications piling up, Indian biopharma industry experts indicated. These metals find use in areas ranging from blister packaging to asthma inhalers to an array of medical instruments and devices. Metered dose inhaler canisters, for instance, are made of stainless steel or aluminium, while nickel alloys and stainless steel are used in implantable medical devices, ranging from orthopedic applications such as joint replacements to stents for angioplasty.

“Packaging costs (blister packs, roll on pilfer proof caps), asthma canisters could all be impacted while upcoming manufacturing facilities may also have to factor in cost escalation,” a pharma industry expert told *Scrip*, though all eyes will be on local suppliers of these commodities.

Others noted how the Indian industry is already facing some of these headwinds as commodity prices have surged which, when combined with higher prices of active pharmaceutical ingredient (APIs) and logistics, could put pressure on margins.

Price increases in APIs and key starting materials have been sharp over the past

quality approaches in new technology areas such as mRNA and do varying international regulatory standards pose challenges? Is the USP- South African Health Products Regulatory Authority MoU a step towards harmonization?

Matruprasad Priyadarshi: Since the application of mRNA technology to therapeutic product is still relatively new, regulatory guidelines and industry best practices related to quality in development and manufacturing are still evolving. A set of commonly agreed assessment methods can help provide Low and Middle Income Countries (LMIC) the opportunity to advance their local operations without having to develop their own methods, and it encourages regulatory predictability.

USP has decades of work in LMIC - training pharma professionals (manufacturers and regulators) in both drug ingredients and finished drug product production to help ensure poor quality products don't reach the market. Both the increased awareness of supply chain vulnerabilities and the number of countries looking to strengthen domestic pharmaceutical production have opened a window of opportunity to maximize the impact of USP standards, advocacy, and capability building programs.

Looking ahead, we will continue to expand our work to support quality along the continuum of the medicine supply chain. Our capability-building work help manufacturers and regulators around the world have access to

few years – for instance nimesulide prices were up 63% in March 2022 from December 2019, while paracetamol prices have seen a 132% jump during the period. Similarly, shipping freight rates from North America, for example, are said to have seen average price increases of over 60% in January 2022 versus pre-COVID-19 times, as per some industry estimates.

Medicine Supply Map

Meanwhile, USP, more widely known for developing quality resources and standards for medicines, dietary supplements, and food ingredients, has been engaged in efforts aimed at identifying vulnerabilities in the upstream pharmaceutical supply chain and providing insights that can inform risk mitigation strategies and

investments, and policy changes that build supply chain resilience. It is also playing a role in developing common approaches for managing quality in new technology areas such as mRNA-based therapies. (See Box)

tools and technologies to help strengthen quality systems in their own countries.

USP has published guidelines that include analytical methods to support developers, manufacturers, regulatory agencies, and national control laboratories worldwide. Approval of products based on mRNA technology is still relatively new, and regulatory thinking is still evolving. By providing these draft guidelines, USP is supporting a shared understanding of overall mRNA quality attributes among manufacturers and regulators as adoption of this technology grows.

Priyadarshi referred to how USP helped address supply-chain challenges and emerging quality and safety concerns with medicines caused by the surge of substandard and falsified health products used to treat and help prevent COVID-19, in collaboration with public health organizations, pharmacopeias, manufacturers and regulators around the world.

The pharmacopeial group also offered free access to relevant chapters on USP–NF Online, its compendium of quality standards. “We also offered technical assistance and support on issues such as vaccine handling and administration, hand sanitizers, and raw material selection and testing,” the executive added.

More recently USP released its Medicine Supply Map, a first-of-its-kind information system that identifies, characterizes and quantifies risk in the upstream pharmaceutical supply chain. The map shows significant concentration of API sites in India and also signals potential supply chain weaknesses.

The USP executive did not specifically indicate whether the map is a “live” one incorporating additions/deletions and/or compliance updates as well to ensure better assessment of supply

chain risks but stressed that it can be used by stakeholders to prioritize supply chain investments to help lower drug shortages.

At the time of releasing initial findings from the map project USP CEO Ronald Piervincenzi underscored that without visibility into the medicine supply chain, “preparing for the next crisis is not possible.”

While there has been an increase in US API production capacity, Piervincenzi, in an interview with *Scrip*’s sister publication the *Pink Sheet*, also pointed out that “when you look at the total drug supply, it was almost inconsequential.”

USP Map Charts Way To Medicine Supply Resiliency

By [Bowman Cox](#)

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Supply chain project shows which drug products are at greatest risk in different scenarios – and which responses would do the most to prevent shortages. Officials from the pharmacopoeial group share how it works and what it can do to help bake in resilience against pandemics, natural disasters, trade wars and shooting wars.

[Read the full article here](#)

Building Resilience Rather Than Deglobalization

Government agencies can also use the medicine supply map to help quantify and inform public investment and policy reforms that build more supply resilience and assess the impacts of trade disputes, severe weather events or pandemic-related shutdowns.

Piervincenzi had earlier this year at BioAsia 2022 noted that while actions and behaviors of governments and others over the recent past appear to be about deglobalization, the solution that people are really seeking is resilience. (Also see "[The Golden Winged Warbler And Creating Pharma Supply Chain Immunity](#)" - *Pink Sheet*, 26 Oct, 2020.)

“They are not really seeking deglobalization but actually looking for resilience, which comes from multiple sources including diversification; resilience also comes from finding other sources even from outside a given country - more countries, not one but two-three-four,” he said at a panel discussion moderated by this *Scrip* journalist.

That, in other words, implies leaning into globalization even further to create the resilience without having a 'single reliance', Piervincenzi underscored.

“There are some counter options that can shift the discussion to building resilience rather than deglobalizing, which would be much better for everyone economically, politically, and better for the industry,” the executive declared.

As nations continue to grapple with supply chain disruptions triggered by trade disputes, severe

weather events or pandemic-related shutdowns, the need for increased geographic diversity of pharmaceutical ingredient sourcing and manufacturing has become clear, experts emphasize. Public and private sector investments to strengthen localized manufacturing and sourcing of critical medicines and ingredients will be critical.

However, such changes will require time and appropriate planning as the world "reimagines" how more resilient medicines supply chains can ensure that public health needs are met, these experts added.