Evidence Generation to Inform Policy

USP will generate and disseminate evidence upon which informed choices can be made for investment in regulatory and quality systems, and reforms to regulatory paradigms that advance quality, patient safety, and public health.

Year 2 Update

Policymakers and stakeholders around the world recognize that the COVID-19 global public health emergency brought to the forefront long-standing vulnerabilities in the medicines supply chain. As the pandemic enters an endemic phase in some regions, factors including geopolitical dynamics, potential natural disasters, and disruptions due to factors yet unknown necessitate heightened efforts to build a more resilient global medicines supply chain to help protect and improve public health. USP has devoted considerable effort to advancing medicines supply chain resilience by engaging directly with global stakeholders to understand related challenges and opportunities, and to inform policy recommendations, informational materials, and advocacy. USP has also continued to expand medicines quality-related research to build strong evidence and materials to advance policy advocacy and capability building essential to medicines supply chain resilience.

Key areas of progress over the past fiscal year include:

Supply Chain Resilience Dialogue and Insights – USP launched the three-part Convention Exchange series to bring together stakeholders with diverse perspectives and generate dialogue to inform policymakers’ understanding of supply chain vulnerabilities, their potential impact on the availability of quality medicines, and USP solutions to bolster supply chain resilience. Topics included lowering barriers to the adoption of advanced manufacturing technologies, the requirements for establishing a cycle of preparedness to help withstand disruptions to the supply chain, and reducing antimicrobial resistance through a resilient supply of quality antimicrobials. Notably, the meeting on antimicrobial resistance included a briefing from a USP Quality Institute fellow on research into the link between poor-quality medicines and antimicrobial resistance, and discussion on related policy implications.
Quality Institute Research – The USP Quality Institute sponsors research to inform and enable evidence-based policy decisions that can help increase the availability of quality medicines. During the year, the Quality Institute sponsored several academic fellows who completed primary laboratory research, published several peer-reviewed articles, and presented their work at national and international scientific and public health conferences. Topics included substandard and falsified medications, procurement of materials used for medicines manufacturing, and antimicrobial resistance.

Medicine Supply Map – USP continued to develop and improve its Medicine Supply Map (MSM) surveillance system to identify, characterize, and quantify vulnerabilities in the upstream pharmaceutical supply chain, deliver insights that can guide risk mitigation strategies and investments, and help inform policy changes that advance supply chain resilience. During the year, MSM focus areas included insights into the geographic concentration of pharmaceutical manufacturing and related risks of shortages for critical medicines, including antimicrobials. USP shared related insights with stakeholders to facilitate decision-making aimed at bolstering supply chain resilience.

Public-Private Partnerships – USP engaged with diverse stakeholders through public-private partnerships on supply chain issues to generate dialogue and evidence that inform policy. This included work in USP’s capacity as a Center of Excellence in global medical product quality and pharmaceutical supply chain security, as designated by the Asia-Pacific Economic Cooperation (APEC) forum.

Planned for Year 3

- USP will bring together regulators from the 21 APEC economies at USP headquarters in Rockville for a seminal dialogue on supply chain resilience during the APEC USA 2023 host year.
- USP will publish a comprehensive supply chain report entitled “A Holistic View of the Global Medicines Supply Chain and Recommendations to Improve Resilience and Ensure Access to Quality Medicines.” Based on dialogue and gathered evidence, the report will be positioned as a foundational resource to inform policy reforms, investments, and the utilization of standards to improve supply chain resilience and global public health.
- USP will bolster the ability of its Quality Institute to generate evidence to inform policy that advances supply chain resilience. This will include promoting supply chain-focused work completed by past fellows. It will also include new
Quality Institute-sponsored independent research to assess stakeholders’ perceptions of risk along the global supply chain.

Contact
For additional information on this Resolution, contact Amy. B. Cadwallader, Ph.D., at Amy.Cadwallader@usp.org.