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Resolution

Impact Expansion

USP will expand its public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.

Year 3 Update

USP continued to expand its impact internationally through a range of strategies and initiatives to increase the resilience of the global medicines supply chain. This included efforts to support development of standards for good distribution practices, strengthen capabilities to address pharmaceutical impurities, facilitate innovation, and ensure supplies of quality vaccines and essential medicines around the globe. USP's broader work to advance adoption of USP quality standards, guidelines, and best practices reached more people in multiple regions of the world, helping to strengthen the medicines supply chain and improve patient safety and public health.

Key areas of progress over the past fiscal year include:

Increasing Medicines Supply Chain Resilience – USP engaged stakeholders in Asia, Latin America, and elsewhere to address medicines supply chain vulnerabilities that became even more evident during the COVID-19 pandemic, to help strengthen regulations, and to raise awareness and understanding of how USP quality standards help strengthen supply chain resilience.

- As part of the U.S.'s 2023 host year activities for the Asia-Pacific Economic Cooperation (APEC) forum, USP and the U.S. FDA co-sponsored the APEC Medical Product Supply Chain Dialogue in April at USP headquarters in Rockville, MD. The event convened over 500 stakeholders from 45 countries – representing international regulatory agencies, industry, academia, nonprofits, and multilateral organizations – to discuss public health priorities, the impact of the COVID-19 pandemic on supply chains, and valuable tools available to help ensure supply chain security. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update.)
- The USP Brazil Summit 2023 on Improving Supply Chain Resilience of Quality Medicines was held in Sao Paulo, Brazil, in March. The event convened regulators, industry, academia, and other stakeholders from the region to discuss lessons

learned from the pandemic and strategies to address potential medicines shortages and to prepare for the next public health emergency.

- In Kyrgyzstan, USP advanced efforts to ensure quality at different stages of the supply chain through the Cure TB program, funded by the U.S. Agency for International Development (USAID) and managed by the JSI Research & Training Institute. USP developed procurement guidelines and technical specifications for procurement; warehouse management guidelines recently approved by the ministry of health; and standard operating procedures to support testing the quality of tuberculosis medicines (and all essential medicines) procured by the state. USP also supported the National Reference Laboratory in Kyrgyzstan to obtain ISO 15189 accreditation, a hallmark for standard quality management systems, by helping them to meet biotechnology technical requirements for microbiological safety cabinets. USP also provided training on equipment maintenance for TB diagnostic labs at national and regional levels.

Strengthening Good Distribution Practices – USP continues to support regulators and stakeholders in the implementation of Brazilian good distribution practice (GDP) regulations by providing solutions and standards for capacity building. USP proposed updating a related general chapter with temperature excursion limits for climate zone IVb, which comprises several countries in Latin America, Africa, and Southeast Asia. In addition, a virtual workshop on GDPs – organized by USP in partnership with Brazilian regulator ANVISA and industry and academic stakeholders – convened over 2,400 participants and included USP's guidance on standards and solutions to implement local regulations. The organizing stakeholders from industry and academia included Brazilian drug trade association Sindusfarma, the national academy of pharmaceutical sciences (ACFB/ANF), the Brazilian association of pharmacy and drugstore networks (ABRAFARMA), the Brazilian association of pharmaceutical wholesalers (ABAFARMA), and the Brazilian association of distribution and logistics of pharmaceutical products (ABRADILAN).

Diethylene Glycol and Ethylene Glycol Contamination – The World Health Organization (WHO) urged a call to action after substandard and falsified medicines identified in The Gambia, Indonesia, Uzbekistan, and several other countries were found to contain unsafe amounts of diethylene glycol (DEG) and ethylene glycol (EG) as contaminants. In response, USP developed a toolkit for manufacturers, regulators, and other pharmacopeias to assist in addressing DEG and EG contamination associated with allergy, cold, and cough medicines. USP also participated in a workshop organized by the WHO South-East Asia regional office in Indonesia in May 2023 to help build the capacity of regional regulatory agencies in South Asia to strengthen the upstream supply chain and address the potential for contaminated raw materials.

Controlling the Risk of Impurities – USP supported stakeholders around the world through its solutions to help control the risk of impurities in medicines, including through related USP standards and training.

- USP and the Vietnam National Institute of Drug Quality Control (NIDQC) completed the first part of a joint pilot project, begun in 2021, for post-market testing for nitrosamine impurities in targeted drug products.

USP provided related capability-building efforts through technical assistance, training, and expert guidance to NIDQC laboratory personnel for part one of the pilot, which involves validation of testing methodologies. Part two of the pilot, which is ongoing and involves testing of targeted sartan products, began in early 2023.

- USP facilitated testing for nitrosamines in finished products by the National Control Lab of the Turkish Medicine and Medical Devices Authority. USP provided the lab with nitrosamine impurities reference standards as well as training on nitrosamine testing in line with USP standards.
- USP supported various regulatory authorities in the implementation of impurity testing, including through a USP webinar on impurities in drug substances and drug products presented to regulatory authorities from Kazakhstan, Uzbekistan, Senegal, and Ethiopia.
- USP and the Indian Pharmaceutical Alliance hosted in February a nitrosamine impurities workshop in Hyderabad, India, titled "Nitrosamines Impurities: Analysis, Industry Needs and Regulatory Perspectives." The event convened 270 participants including representatives from industry, academia, the European Directorate for the Quality of Medicines and HealthCare, and regulators from India, Japan, and the U.S. FDA.

Strengthening Regional Relationships and Partnerships – USP continued to strengthen regional partnerships through USP Convention Regional Chapter meetings, strategic additions to USP Convention Membership, and memorandums of understanding (MOUs) in regions around the globe.

- The USP Convention European Regional Chapter launched with over a dozen Member Organizations representing diverse perspectives, including regulatory authorities, pharmacopeias, practitioners, and manufacturers. The inaugural hybrid meeting addressed supply chain resilience, pharmaceutical environmental sustainability, convergence, managing the reduction of nitrosamines, and opportunities to contribute as a USP Expert Volunteer.
- USP conducted meetings of Regional Chapters for Asia Pacific, South Asia, China, Latin America, and Middle East and North Africa.
- USP signed eight new MOUs and renewed two previous MOUs to strengthen regional relationships aimed at fostering collaboration and knowledge sharing, education and training, standards setting, advancing regional manufacturing, strengthening regulatory and laboratory systems, and supporting medicines quality and public health around the world. These included MOUs with regulatory bodies, industry groups, professional associations, and others in regions including Latin America, Asia, and Africa.

Vaccines Quality – USP worked to ensure supplies of quality vaccines in regions around the world.

- In support of the USAID Global Vax Initiative, USP facilitated a four-day visit to vaccine manufacturing sites in Hyderabad, India, accompanied by over a dozen regulators from six African countries – including Ghana, Kenya, Nigeria, Rwanda, Senegal,

and South Africa – as part of our ongoing commitment to strengthening regulatory systems and enhancing quality control capacities in low- and middle-income countries (LMICs).

- USP's Promoting the Quality of Medicines Plus (PQM+) program, supported by USAID, helped national medicines regulatory authorities (NMRAs) put into practice USP's proposed model to build capacity for emergency use authorization for vaccines.
- At the request of the African Union Development Agency (AUDA-NEPAD), PQM+ and the USP Global Health Technical Program developed a framework and five-year strategic plan to advance establishment of an African vaccine lot release laboratory network.
- USP engaged with Kazakhstan's State Center of Expertise and facilitated a webinar on quality assessments of vaccines as the country's pharmacopeia works to include general chapters covering vaccine quality assessment.

Supporting Advanced Therapies in Asia – In May, the USP-APEC Center of Excellence for Advanced Therapies held a two-day virtual training with more than 150 regulators from APEC and beyond on chemistry, manufacturing, and control challenges in chimeric antigen receptor (CAR) T-cell therapy to address knowledge gaps in real world applications. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update.)

Regulatory Capability Building in LMICs – USP continued to advance regulatory capability building in LMICs through a range of initiatives during the year.

- USP's PQM+ program helped increase the number of countries that can reliably test medical products, helping four national quality control laboratories (NQCLs) in Pakistan achieve World Health Organization (WHO) prequalification, helping two new NQCLs in Laos and Mali achieve ISO 17025 accreditation, and expanding the scope of testing in three NQCLs (one in Ethiopia and two in Nigeria). The effort also helped two Pakistan diagnostic labs achieve ISO 15189 accreditation.
- PQM+ began supporting the national regulatory authorities (NRAs) of Lesotho, Malawi, and Panama. In Lesotho, USP supported establishment of their NRA and implementation of related regulatory procedures, regional regulatory harmonization strategy, and protocols. In Malawi, USP conducted an analysis of the NRA and helped revise its strategic plan. In Panama, USP supported lab testing efforts and helped revise the curricula for the University of Panama to institutionalize and standardize information and requirements for a regulatory workforce.
- Through PQM+, USP provided technical assistance to manufacturers in Africa and Pakistan to achieve WHO prequalification, regulatory approval, and availability of quality-assured zinc sulphate treatments to treat childhood diarrhea, a leading cause of death among children under age five.
- USP supported two Ghana regional hospitals in obtaining ISO 15189 accreditation. USP also helped the Chad National Laboratory for Quality Control of Drugs strengthen its quality management system by 50% through hands-on capacity building

efforts in quality management systems, internal auditing, and quality control techniques in physical chemistry and microbiology. In the Solomon Islands, USP built capacity of the Ministry of Health and Medical Service and the National Pharmacy Services Division in the use of minilab equipment.

- With support from the World Bank, USP provided the Democratic Republic of the Congo with lab concept designs for new microbiology and medical devices laboratories and facilitated expansion of national control laboratory testing capabilities.
- USP held a workshop with Bangladesh regulators and industry to strengthen the country's regulatory capacity. The workshop addressed creation of a quality culture and raised awareness of the importance of pharmaceutical reference standards.
- USP presented at a conference organized by the Philippines Food & Drug Administration (PFDA) on "Empowered Regulators Gearing Up for Global Recognition." Convening over 500 staff of the PFDA, the event focused on raising awareness of international regulatory commitments.
- USP's Preferential Access for Regulators (PAR) program continued to provide regulators in LMICs with no-cost or subsidized access to USP educational courses, documentary standards, and reference standards to help ensure access to quality medicines and support medicines supply chain resilience. USP signed 11 PAR agreements and one renewal during the year, covering geographies in the Asia-Pacific, South Asia, Europe, the Middle East, Africa, and Latin America.
- USP conducted a comprehensive analysis of supply and demand for postpartum hemorrhage (PPH) products in sub-Saharan Africa with support from the Reproductive Health Supplies Coalition (RHSC), funded by the Bill & Melinda Gates Foundation. The study pinpointed gaps in access to quality-assured maternal health products. The findings are helping to shape RHSC stakeholder efforts to bolster regional manufacturing of PPH products.
- USP conducted ongoing discussions with the Health Division of the Association of Southeast Asian Nations (ASEAN) Secretariat to combat substandard and falsified medicines in the region.

Planned for Remainder of the Cycle

- USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit, and will work with partners, such as the Alliance for Safe Online Pharmacies, to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- USP will continue to expand regulatory engagement globally – including through formal MOUs – to advance capability building and medicines supply chain resilience. Specific focus areas will include pharmaceutical impurities and complex generics.
- USP will continue to deliver training courses and organized educational workshops to build regulatory capabilities in regions around the world.
- USP will continue to advance stakeholder engagement – including through Convention Regional Chapters – to share knowledge and

expertise and to learn from diverse perspectives around shared priorities on topics ranging from pharmaceutical impurities to adoption of advanced manufacturing technologies. The Sub-Saharan Africa Regional Chapter will launch.

- USP will continue to expand its PAR program to increase access to USP's standards and education programs.

Contact

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