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New Study Recognizes that Public Quality Standards Support U.S. Generics Market

Research identifies link between mandatory public quality standards and lower drug costs

Rockville, MD, November 13, 2019 — A new study released in the journal PLOS ONE found that on average, drugs with a public quality standard developed by the U.S. Pharmacopeia (USP) had approximately 50% more generic manufacturers compared with medicines without such a standard. Researchers from Johns Hopkins University, who developed the study, concluded
that quality standards helped facilitate pharmaceutical competition and reduce prescription drug costs in the US.

Public quality standards for medicines – also known as monographs – that are developed by USP set specifications for purity, potency and other quality attributes, which assist generic manufacturers in more efficiently gaining regulatory approval for drug products. Researchers estimated these standards increased competition in the generic medicines market and reduced overall prescription drug costs by $11 billion in 2015 and 2016.

“Mandatory, public quality standards have played a critical role in building the public’s trust and confidence in medicines and have helped make America’s drug supply among the safest in the world,” said Ronald T. Piervincenzi, Ph.D., Chief Executive Officer, USP. “While we have long had anecdotal evidence about how our work positively impacts access to medicines, the Johns Hopkins study is the first to provide data on the economic benefits of mandatory public quality standards and links USP monographs to increased market competition and lower drug prices.”

The Johns Hopkins study provides evidence in support of USP’s Generics Access Plan, which launched in January to help increase access to medicines by facilitating generic competition through new and revised quality standards and related activities. USP’s Generics Access Plan supports the FDA in its efforts to encourage development of new generic medicines to promote competition, help reduce drug prices and improve access to medicines for Americans.

USP develops science-based quality standards, and adherence to them is required for all corresponding drug products marketed in the U.S. regardless of where in the world they are manufactured. A network of over 800 scientists and other experts from around the world volunteer their time and expertise to develop the standards through a collaborative, transparent process. Once developed, the standards are available publicly and relied upon by healthcare professionals, regulatory and enforcement agencies, manufacturers and others. The starting

point for the development of a drug monograph is often a donation of scientific methods for materials from a pharmaceutical manufacturer.

“As this and future studies corroborate the savings achieved through the availability of USP monographs, we also want the manufacturing industry to recognize the important role they play in donating their scientific methods to create standards that improve access to quality medicines,” said Dr. Piervincenzi. “We want to build on the collaborative process of public standards development to bring critical therapies to patients by ensuring a robust generic market.”

The study, entitled, “Association Between US Pharmacopeia (USP) Monograph Standards, Generic Entry and Prescription Drug Costs,” was supported by a grant and technical assistance from USP.

About USP
USP is an independent scientific organization that collaborates with the world’s top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people world-wide. For more information about USP, visit www.usp.org.

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