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Session 339 – Drug Shortages: Causes, Current State and Path Forward

As the number of patients with life-threatening conditions such as cancers and cardiovascular diseases has steadily increased, the topic of drug shortages has grown into corresponding importance.

Erin Fox, PharmD (Director, Drug Information Service, University of Utah Hospitals & Clinics) opened the session *Drug Shortages: Causes, Current State & Path Forward* by examining *Current Trends in Drug Shortages*. Erin introduced the University of Utah Drug Information Services and its contribution to the American Society of Health-System Pharmacists (ASHP) database that identifies drug shortages in the US. She explained the difference between ASHP and FDA drug shortage tracking: ASHP focuses more on immediate shortages, which affect how clinicians treat today's patients; FDA tracks shortages in medically necessary products that have significant impacts on public health. ASHP drug shortage numbers are consistently higher than FDA's because ASHP also tracks biologic and device product shortages. In Dr. Fox's analysis, the number of new shortages is decreasing but, overall, shortages are still increasing because active shortages are not getting resolved fast enough.

She further explained how fragile supply chain systems can cause various manufacturing problems that eventually lead to drug shortages, and the impact of drug shortages on medical treatments, including the medical error of substituting for unavailable drugs with possibly fatal consequences for patients. Dr. Fox concluded by encouraging flexible, tenacious, communicative and strategic planning when a shortage is foreseen.

Session Chair Marta E. Wosinska, PhD (Director for Economics Staff, Office of Planning and Analysis, CDER) specifically focused on the *Economic & Technological Drivers of Sterile Injectable Drug Shortages*, which make up about 75% of current drug shortages. She also pointed out the impact of production problems on drug shortages: Sterile injectable drug manufacturing is highly concentrated in a small number (about 12) of sites operating in the US, so whether it's a brand or generic product, there are no alternative manufacturing facilities when production line problems arise. Dedicated and specialized production lines, and cross-contamination risks, make it even harder for more than one product to share manufacturing facilities.

Dr. Wosinska explained that FDA currently has limited authority to force companies to increase production due to shortage concerns, but does have early notification requirements for manufacturers to report when the company assesses a potential drug shortage; although there is no penalty for failing to notify, she explained, industry has been actively reporting shortages.

She also explained FDA's role in a drug shortage: Coordinating to prevent a shortage, arranging for increased production with other companies, or seeking out import options from other countries. Other tactics include extending expiration dates or transferring production to a different site that the manufacturer may have available. FDA currently has only 11 full time Drug Shortage staff, so the agency tries to use its regulatory discretion to encourage continued production, or even temporarily allow import drugs without going through the complete approval process, for affected products when necessary. She repeated the importance of early notifications which provide the agency more time to respond to and prevent a possible shortage.

Dr. Wosinska concluded her presentation by suggesting ways to recognize and reward quality in manufacturing, such as standard quality metrics. Public recognition of good or improved quality can also encourage manufacturing facilities to maintain a level of quality and further prevent issues that could cause drug shortages.

Christa Wirthumer-Hoche, PhD (Member CMDh, Head of Institute, Deputy Head of Austrian Medicines and Medical Devices Agency [AGES], Austria) delivered the European perspective on the *Availability of Medicinal Products in the EU*. She explained how, similar to the US, factors such as manufacturing problems, impurities, lack of production capacity and other issues were causing drug shortages in the EU; in the same way, an accurate assessment of drug shortage statuses is also hard to capture in the EU. Member States tend to rely on early detection and thorough communication from the marketing authorization holder to identify drug shortages, and from the marketing authorization holder and healthcare professionals to identify alternative treatments.

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