



Navigating Supply Interruption and Drug Shortage Challenges

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“Today, US patients and providers are struggling with the impacts of historically unprecedented medicine shortages, which are primarily driven by deflated prices for generics.” ¹



- “Nearly 9 of 10 prescriptions filled in the US today are for generics”. ²
- “A single generic competitor alone can reduce prices by 30%, and competition among five generics has been associated with up to 85% lower prices.” ⁴
- “More than 131 million people, that’s 66% of US adults use prescription generics medicines.” ³

Patients rely on manufacturers to have quality medicines readily available.... at any time.... at an affordable, low-cost... regardless if it is profitable for the company.

This is a critical challenge that generic drug manufacturers contend with each day.



Supply Interruption and Drug Shortage Complexities

Increasing Pricing & Economic Pressures

- Thin margins
- Manufacturing Complexity
- Supply Chain Vulnerabilities

Regulatory Hurdles

- Increased reporting
- Generic Approval Competition
- DEA Quotas & Allocations

Market Demand Instability

- Consolidated purchaser market
- Restrictive insurance plans



How can WE improve patient access?

From a regulatory perspective.....

- Change approach to benefit/risk assessments that allow more generics on the market in instances of prolonged drug supply interruptions and longer-term drug shortages.
 - Drug shortage support incentives
- Enable faster access to US patients with generic medicines approved by non-US trusted, competent authorities.
 - Shift beyond regulatory discretion & enable other regulatory approval pathways
 - Aligned regulatory reviews across countries, one voice of quality (1VQ)

From an industry perspective.....

- Continue e2e product lifecycle derisking programs and build quality and compliance fundamentals into everything we do
- Invest in talent capabilities, build knowledge management programs and share lessons learned, avoid reoccurrence.
- Proactively identify signals, intervene and mitigate, monitor and sustain CAPA effectiveness
- Invest and modernize manufacturing software, instrumentation, equipment and facilities



References

¹ **Sandoz: “Solving America’s Drug Shortage Dilemma, For Good”.** Accessed October 2024 @ www.generics.citeline.com.sandozsolving-americas-drug-shortage-dilemma-for-good92424.pdf (citeline.com).

² **US Food and Drug Administration (FDA). Generic Drugs.** Accessed October 2024 @ [Generic Drugs | FDA https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs](https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs).

³ **Georgetown University Health Policy Institute. Prescription Drugs.** Accessed October 2024 @ <https://hpi.georgetown.edu/rxdrugs/#:~:text=A%20vital%20component%20of%20health,United%20States%20%E2%80%94%20use%20prescription%20drug>
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⁴ **US Food and Drug Administration (FDA). Generic Drug Facts.** Accessed October 2024 @ [Generic Drug Facts | FDA https://www.fda.gov/drugs/generic-drugs/generic-drug-facts](https://www.fda.gov/drugs/generic-drugs/generic-drug-facts).

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