FDA Public Meeting on Enhanced Drug Distribution Security at the Package Level Under the DSCSA

American Pharmacists Association

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How is implementation of the 2023 enhanced system requirements progressing for your organization?

What challenges is your organization facing?

Are the proposed recommendations in FDA's guidance on enhanced drug distribution security at the package level helpful to achieve compliance with 2023 enhanced system requirements? If not, what additional information would be useful?

2023 requirements are just that…requirements --- not a “system”

“Enhanced system” is a misnomer and confusing

- DSCSA calls for requirements of enhanced drug distribution security
- No single system is being developed
- DSCSA requires trading partners to have “systems and processes”

Keep it simple – stick with the basic requirements

- Assess current and predicted state of readiness across the supply chain
- Set forth a tiered approach to implement full capabilities and requirements
  - Reassess as systems, processes, experience matures
- Stick to the basics….avoid “nice-to-have” elements

Consider risk-based reconciliation

- Available systems, processes, and resources will make it difficult to:
  - Automate reconciliation
  - Reconcile each product package with transaction documentation
  - Automatically upload information

- Pharmacies do check inbound orders

- Identify risk-based reconciliation and verification if reason to believe product may be suspect or illegitimate

Are there areas in which FDA could provide more clarity?

Please clarify:

- What is “appropriate access” to individual systems
- Expectation for “facilitates the gathering”
- Handling clerical errors and discrepancies
- Systematic approach to handling alerts

? Questions ?

Thank You FDA!!

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