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Worldwide Regulatory Updates



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- **U.S. DSCSAD**
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U.S DSCSA

- The FDA published its final guidance on “Verification Systems” for the DSCSA.
- The FDA has released its DSCSA Communication Portal, with instructions for trading partners to confirm their DSCSA role and to manage notifications/requests from the FDA.
- A GS1 US working group provided its non-binding recommendations for managing transition inventory; i.e., implications on further transactions on packs originally received with lot-level T3 that now require pack-level T2.

Brazil

- ANVISA enacted a 90-day public consultation on a governmental workgroup’s

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"e-Leaflet" approach.

EU FMD

- Belgium: The country's "Full FMD" implementation is slated to go into effect on the FMD's five-year anniversary on February 9, 2024.
- Romania: The Government has granted power to the NCA to introduce sanctions for non-FMD compliance.

India

- GS1 Global Healthcare released a discussion paper to recommend a more specific standards-based approach to the "Top 300" brands barcoding requirement for domestic medicines.

Jordan

- The government has delayed its serialization and barcoding requirement to Jan. 1 2024.
- Romania: The Government has granted power to the NCA to introduce sanctions for non-FMD compliance.

TraceLink is the world's largest digital supply network for the pharmaceutical industry supply chain. It enables firms in the healthcare sector to achieve greater transparency, agility, and resiliency in pharma supply chains and enhance pharmaceutical supply chain security through real-time information and insights sharing. Providing firms in the pharma value chain with the tools and advanced capabilities they need to improve pharmaceutical supply chain management, TraceLink's technology is powering the digital transformation of the global medical supply chain and accelerating pharmaceutical supply chain optimization. TraceLink helps pharmaceutical supply partners better manage and build

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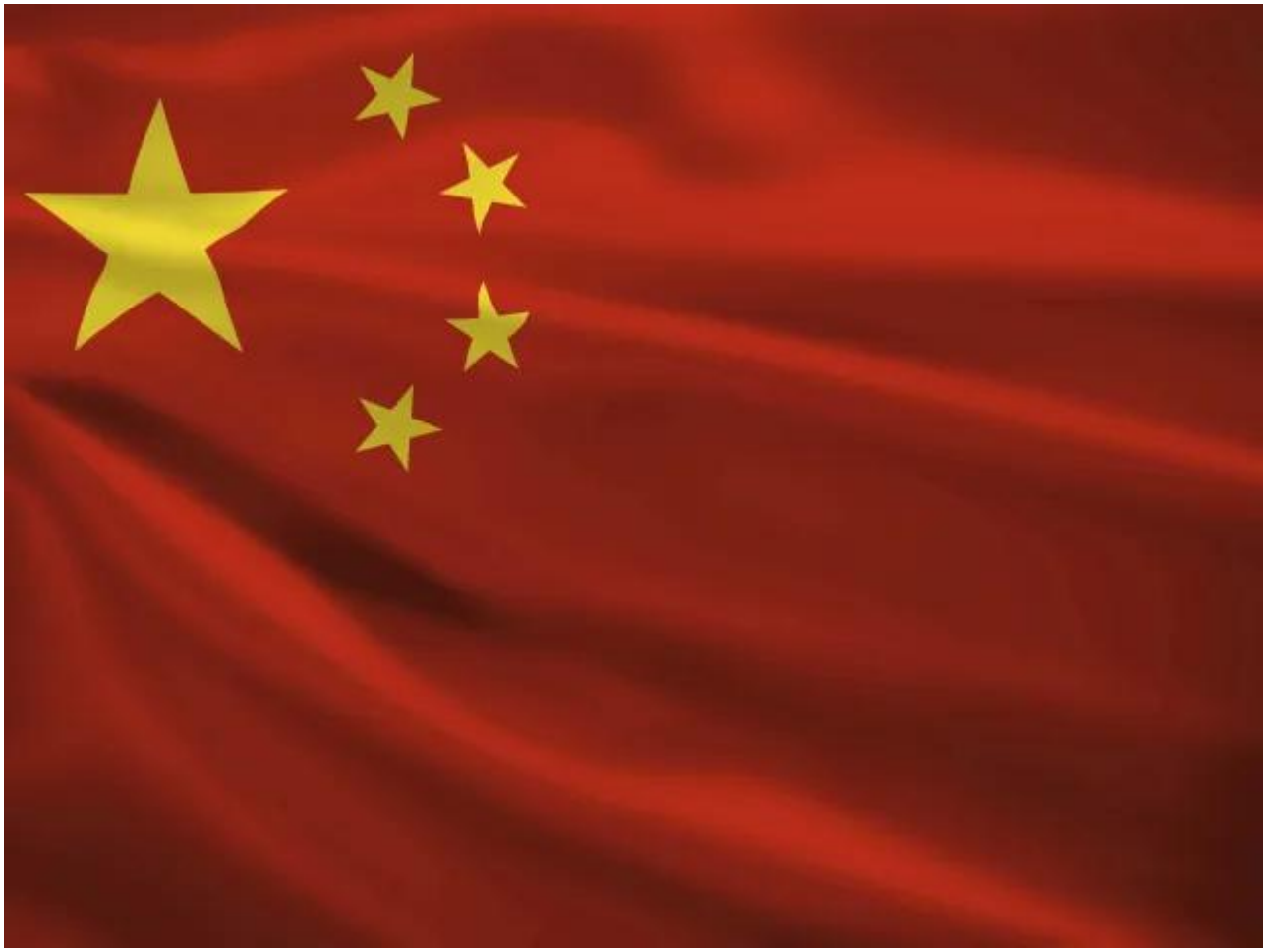


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