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China Progress Report:
Industry Driving Discussions on
Encoding and System
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There are new signs that the implementation of China's comprehensive track and trace system is gaining momentum, including the growing recognition of the GS1 standard as a second encoding option in China.

With the passing of the December 31 interim deadline for serializing pharmaceutical products of national drug centralized procurement and other key product categories, the industry is now awaiting updates from the National Medical Products Administration (NMPA) on the status of the country's 3-tier Drug Information Traceability Supervision System. Of particular concern is the development of the NMPA's Collaborative Service Platform and how this "middle-tier" system will connect with the various traceability systems being implemented by companies distributing products in China, whether they are third-party solutions from TraceLink, Tencent, or AliHealth or if they are self-built.

NMPA delivers a year-end progress report

At the December Smart Health Expo NMPA presented the keynote address, "Action

Plan for Accelerating the Smart Supervision of Drugs by the NMPA,” which included an update on the agency’s progress on building its data centers and application platforms. Milestones included:

- Construction of its Drug Administration Cloud
- Integration of 38 decentralized systems into the smart supervision platform
- Migration and deployment of 34 business systems

In addition, the year saw the establishment of the NMPA’s vaccine traceability collaborative service platform with the integration of the country’s provincial immunization systems.

Multiple encoding options a key focus for 2021

In the breakout session that followed, NMPA led discussion around a range of topics affecting companies distributing products in China. Key takeaways included:

- The NMPA Informatics Center intends to promote establishment of a drug traceability system to satisfy the December 31, 2020 requirement for traceability of the four key drug classes: national centralized drug procurement, narcotics, psychotropics, and blood products.
- NMPA recognized the existence of multiple coding approaches and multiple systems in the new landscape and the role of its Collaborative Service Platform (CSP) as a “bridge” or translation layer between enterprise or third-party traceability systems and the supervisory systems.
- NMPA identified several issues facing the industry as it prepares for the new regulatory requirements:
- Multiple coding schemes and challenges the industry (and the NMPA) faces today in selecting and implementing product coding and posits a “gradual transition” towards unification.
- Multiple drug traceability systems and the lack of unified standards and capabilities in drug traceability systems and the consequent challenges in data sharing across the supply chain.

- How to handle consumer queries on traceability data.

Stay informed with TraceLink's China Special Interest Group

This new activity points to an extremely busy year ahead as China continues to refine its track-and-trace regulations, implement their compliance systems, and establish readiness milestones and interim deadlines. As 2021 unfolds, TraceLink's China Special Interest Group will continue to monitor new developments throughout the year to ensure that our customers and their partners have the information and insight they need to ensure compliance and business continuity. Stay up to date on China's compliance regulations with our [weekly regulatory updates](#).

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UNIQUE IDENTIFICATION CODE FOR DERMOMESTHETIC PRODUCTS

IBSA's Internal Serialization Procedure for Medical Device Products

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Key Challenges & Solutions

IBSA's internal serialization procedure for medical device products was a complex task. The challenge was to create a unique identification code for each product, ensuring that the code was secure and could be used to track the product throughout its lifecycle. The solution was to use a combination of a barcode and a QR code, which allowed for easy tracking and verification of the product's authenticity.

Key Activities and Resources

The key activities involved the development of the internal serialization procedure, the implementation of the procedure, and the ongoing monitoring and maintenance of the system. The resources required included a team of experts in serialization, a secure database for storing the product information, and a reliable communication system for transmitting the data.

Outcomes

The outcomes of the project were a significant reduction in product counterfeiting, improved product traceability, and enhanced customer satisfaction. The success of the project was measured by the number of counterfeit products identified and the number of customer complaints resolved.

Recommendations

The recommendations for future projects include the use of a secure database, the implementation of a reliable communication system, and the ongoing monitoring and maintenance of the system. It is also recommended that the project be documented and shared with other organizations in the industry.

Case Study: IBSA | Using Serialization to Ensure Product Integrity

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