UDI progress in China

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Context

- Background
- General Idea
- Highlights
- Next steps
- summary

Background – Policy

On July 2015，Opinions of the General Office of the State Council on Accelerating the advancement of the Construction of important product Information Traceability System

Promote the construction of food and drug traceability systems. Food: Supervise and guide manufacturers to establish a quality and safety traceability system according to the laws; Drug: promote the traceability of full variety of drugs during the whole process, and build and improve the drug traceability system.

On September 2016 , Opinions of CFDA on Promoting the Food and Drug Manufacturers to Improve Traceability System

Encourage drug and medical device manufacturers to assign unique identifiers to the **smallest sales units of products**, to facilitate the identification by operators and consumers.

Implantable medical devices shall be marked with the manufacturer’ s name or trademark, batch code (batch number) or serial number to ensure traceability

Background – Policy

On Feb 2017,The 13th Five-Year National Drug Safety Plan

Formulate medical device coding rules and build a medical device coding system

On June 2018, the draft of Amendments of Regulations for the Supervision and Management of Medical Devices

Medical device shall be assigned a Unique Device identifier. UDI shall comply with UDI rules formulated by NMPA.

Background – Market

Government departments:

NMPA: based on the lifecycle administration by information system, develop the “index” for the Regulatory Big Data; National Health Commission: procurement of high-value consumables; , the State Medical Insurance Administration: reimbursement management & payment system

Manufacturers: product information traceability, logistics management, adverse event analysis & evaluation

Distributors: product identification, logistics management, invoicing management

Users: product identification, procurement management, device use management, expense management

Patients: product identification, informed consumption

A common demand of stakeholders along UDI supply chain

Background – International

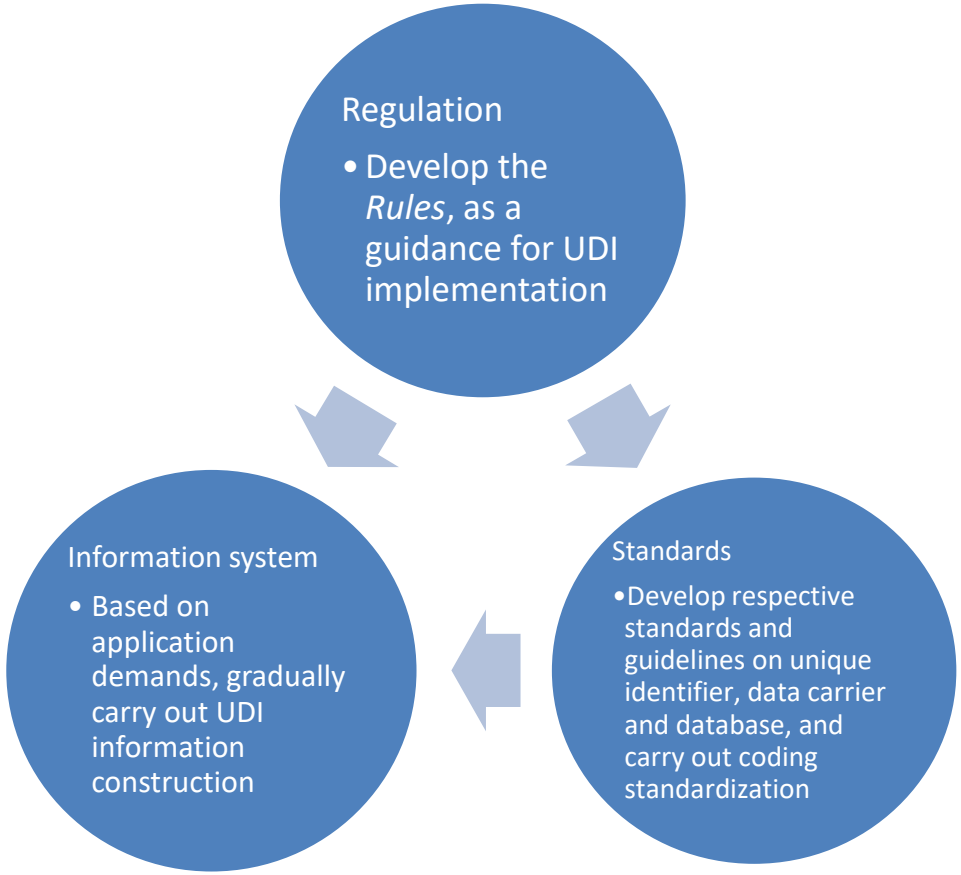
UDI regulation focuses around the world

IMDRF: UDI Working Group was formed up in 2012, and in 2013 IMDRF UDI Guidance was released and UDI Working Group was closed; in 2017 UDI Application Guide Working Group started to work on international coordination around the implementation level, with relevant guideline under development.
FDA: UDI rules were issued in 2013 and have been taking effect for 4 years since 2014. Currently, UDI is implemented in Class II products and above.
EU: Medical device regulations were issued in 2017, which had made provisions on UDI. Relevant rules have not yet been released.

General Idea

- Positioning: identification system, instead of a traceability system
- responsibility: guided by government, undertaken by enterprises
- Construction principle: based on national conditions with reference to international standards
- Construction content: UDI + UDI database
- Implementation steps: preparation - pilot - first stage - second stage – as a whole

General Idea

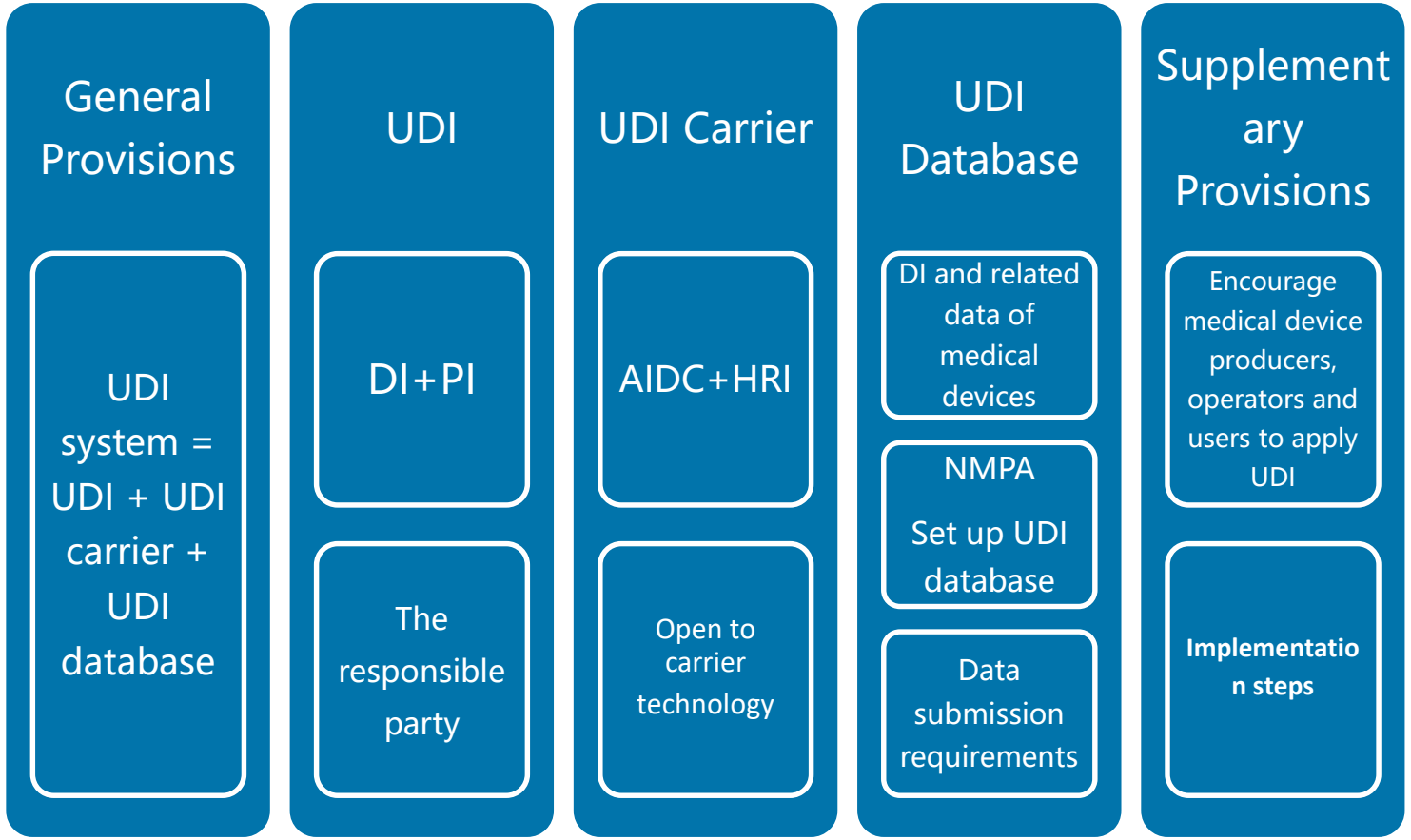


Highlights

- **Open for comments on February 26, 2018**
- **Open for comments on August 22, 2018**
- ***Rules for Unique Device Identification System***

two rounds of public consultation

Outline


General Provisions
UDI system = UDI + UDI carrier + UDI database
UDI
DI+PI
The responsible party
UDI Carrier
AIDC+HRI
Open to carrier technology
UDI Database
DI and related data of medical devices
NMPA
Set up UDI database
Data submission requirements
Supplementary Provisions
Encourage medical device producers, operators and users to apply UDI
Implementation steps

Next Steps

Formulation of Supporting Standards

Construction of UDI Database

UDI Pilot

Summary

UDI & Traceability:

- The UDI system is a medical device identification system. The purpose is to build a system that can fully identify the life cycle of a device. It only includes the static information of medical device products, and does not include dynamic information such as production plans and flow direction.

Linking UDI database with other regulatory databases:

- Through the linkage between different databases (such as registration database, adverse reaction database, etc.), reduce enterprise inputs and improve data accuracy, thereby contributing to the Regulatory Big Data.

the active application of UDI

- The benefits of UDI can only accrue if all stakeholders, from the manufacturer to healthcare providers and patients, use UDI throughout their workflow systems. (IMDRF UDI Guidance 2013)

Thank You !