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 August 2018, Deepening the Reform of the Medical and Health System

Formulate the coding rule and explore the application of standardized coding in registration, procurement and use of high-value medical consumables

On March 2019, 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 – Stakeholders

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

Hospitals: 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 upon final approval

FDA: UDI rules were issued in 2013 and have been taking effect for almost 5 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. Some guidelines have already been published

Other countries:

General Idea

Positioning: identification system, instead of a traceability system
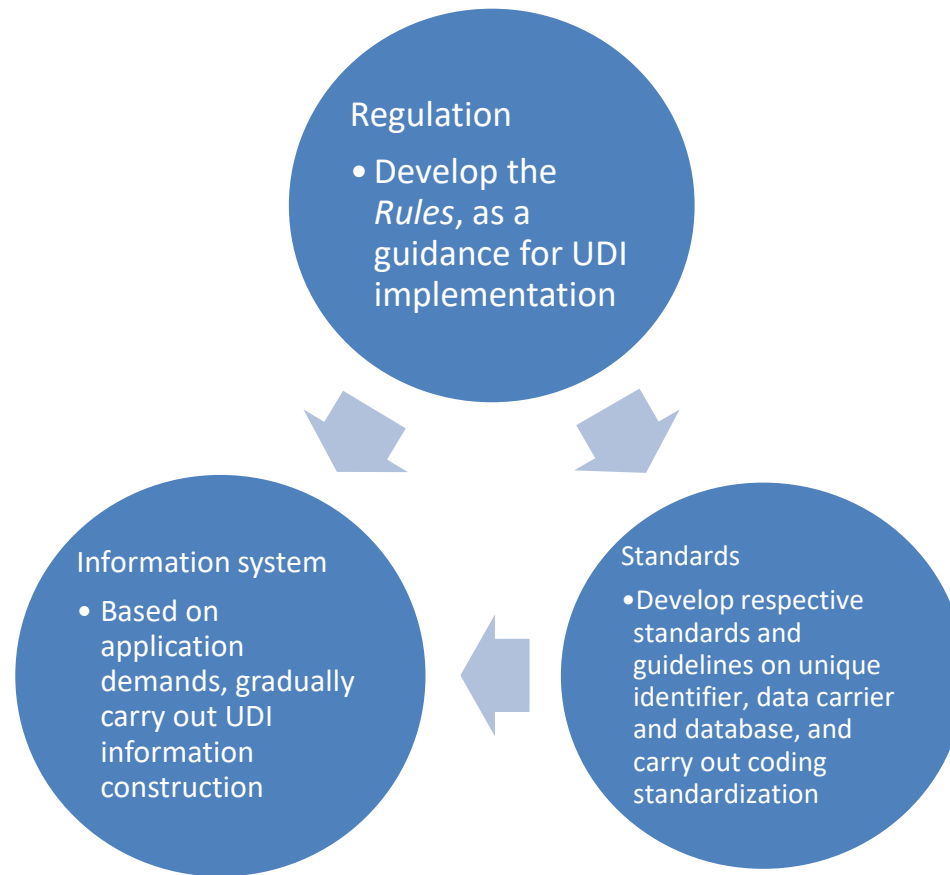
responsibility: guided by government, undertaken by enterprises

Construction principle: based on national conditions with reference to international standards
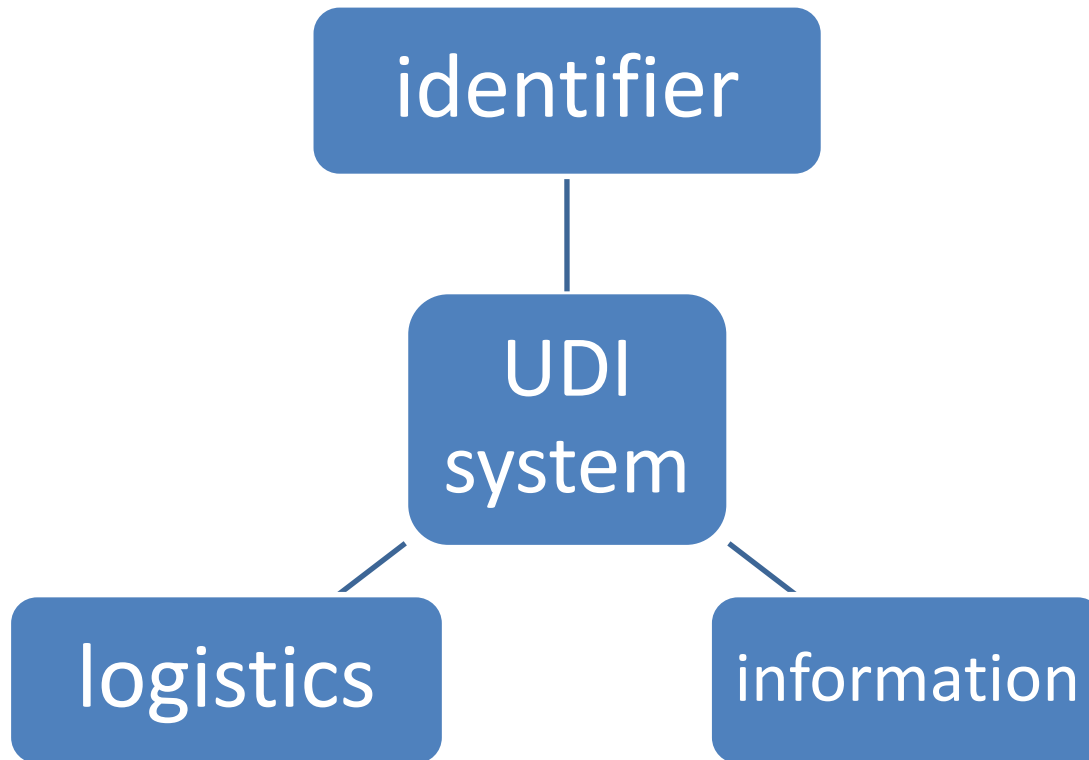
Construction content: UDI + UDI database

Implementation steps: preparation - pilot – step by step considering the product risk and category

General Idea

Regulation

- Develop the *Rules*, as a guidance for UDI implementation

Standards

- Develop respective standards and guidelines on unique identifier, data carrier and database, and carry out coding standardization

Information system

- Based on application demands, gradually carry out UDI information construction

Highlights – Role

identifier

UDI system

logistics

information

Highlights – Rule Marking

2006 Shanghai pilot on part of the high risk implants

3 major field investigations on UDI （2014，2016 and 2018)

Keeping performing fundamental research on UDI system

Development and improvement of the proposed rule starting from 2014

Highlights-Proposed Rule

- **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

Highlights-Outline

General Provisions	UDI	UDI Carrier	UDI Database	Supplementary Provisions
UDI is a system	DI+PI	AIDC+HRI	DI and related data	Encourage to use UDI
construction principles	The responsible party		NMPA Set up UDI database	
responsibilities	Issuing Agency	Open to carrier technology	Data submission requirements	Implementation steps
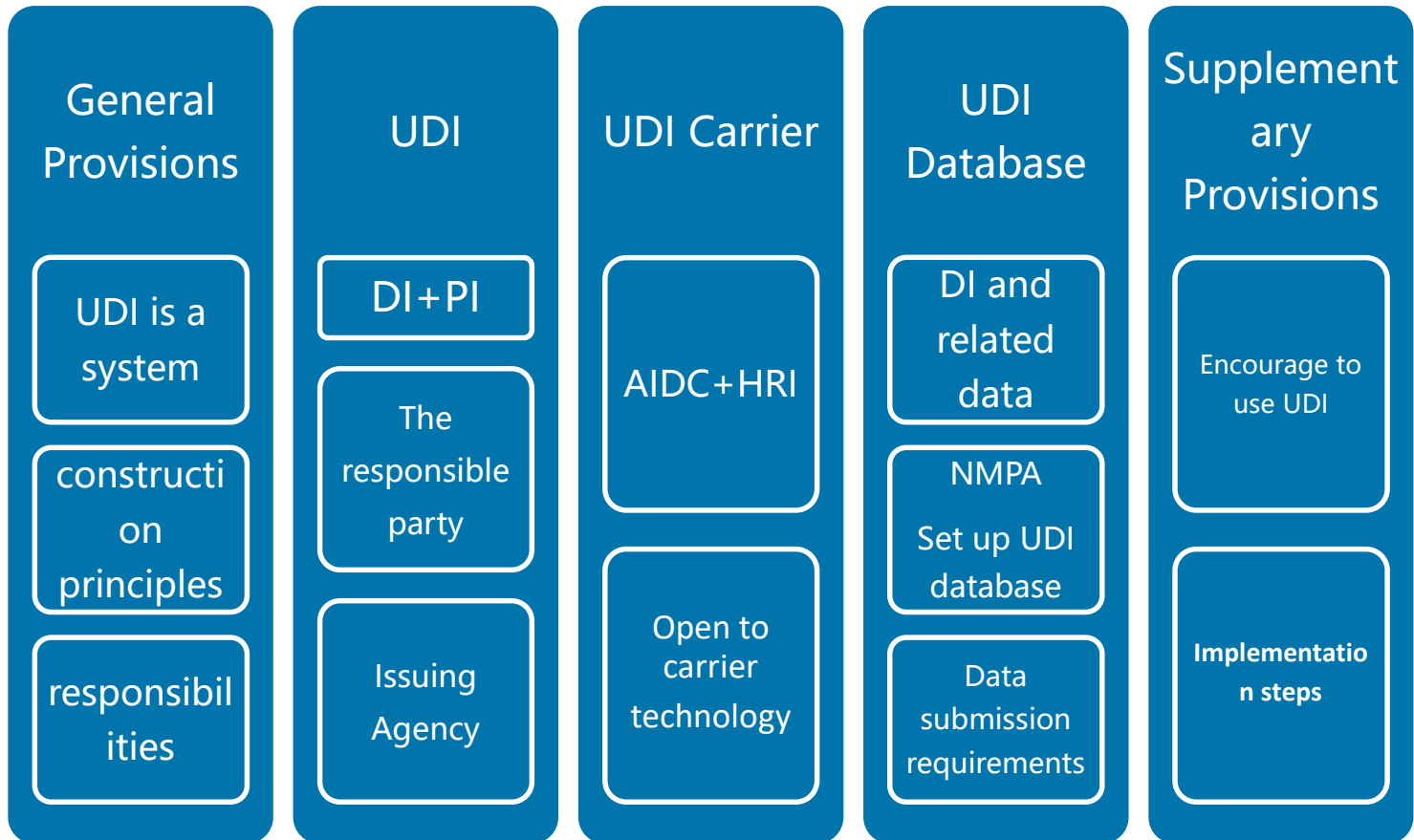
Highlights-Issuing Agency

- **Reforms to streamline administration, delegate powers, and improve regulation and services**

- **ISO 15459 series status in China and Standard law**

- **Current medical device coding situation in China**

- **International standard are recommended**

Highlights-Supporting Standards

Fundamental standards

- Fundamental requirement of unique device identifier YY/T 1630-2018
- Basic terms of unique device identification system

Information-based standards

- UDID Data Filling Guidelines
- Basic Data Set of UDI system

Next Steps

Formulation of Supporting Documents

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)

Using the invisible hand

- Open to the universal standard and let the market to choose the fittest

Find a balance

- UDI system is a balance for all the stakeholders

Thank You !