UDI Development in AHWP and China UDI System Introduction

UDI

Reporter:

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WG9 (U&N)

- Chair: Jun LI (Regulator)
- Co-Chair: Victoria QU (Industry)
- Secretary: Li YI (Regulator)

❑ **Active members**

- Regulator: 8 (Saudi Arabia, Singapore, Thailand, China, Chinese Taipei)
- Industry: 15

The Goal and Objective of WG 9

WG 9

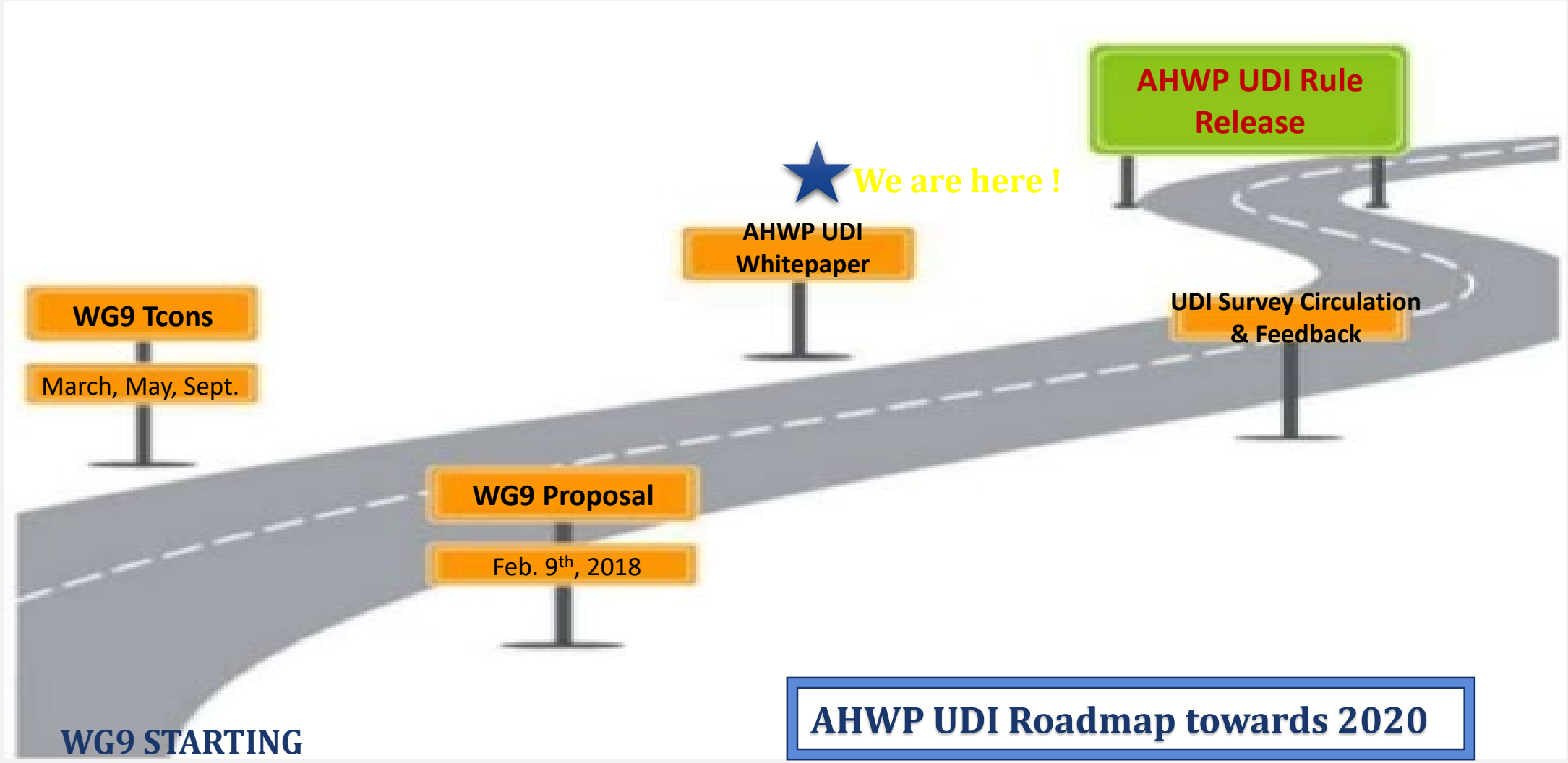
UDI & Nomenclature

- Establishment of **a communication platform** between the regulatory agencies and industry

- Promote coordinative and **harmonized approach of UDI and nomenclature** during the development and implementation of related regulations and policies;

- Urge **global convergence of medical device UDI and nomenclature regulations** on behalf of the AHWP members and to actively participate in the coordination of international harmonization initiatives.

2018-2020 UDI Road Map



UDI Survey & Analysis

- The content of AHWP UDI survey - 25 questions including single choice, multiple choice and open questions distributed among WG9 members.

General requirements of the UDI system components including UDI, UDI carrier and UDI database

Implementation strategies such as transition period, alternative and exemption

The purpose and benefit of UDI system

The responsibility of the key stakeholders

Review of 2019 Activities - UDI

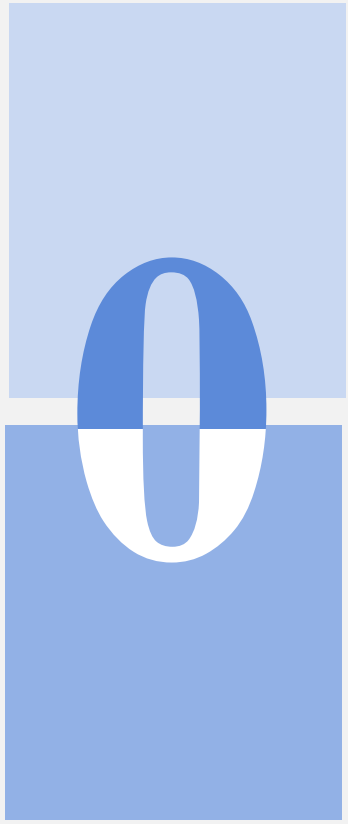
Send the survey to AHWP members	April 2019
Develop the AHWP UDI Whitepaper and **circulate for public consultation in Sept. 2019.**	Q3 2019
Whitepaper to be presented and endorsed at the AHWP Annual Meeting	Nov. AHWP Annual Meeting

China UDI System Introduction

Policy Background

Main Contents of Rules

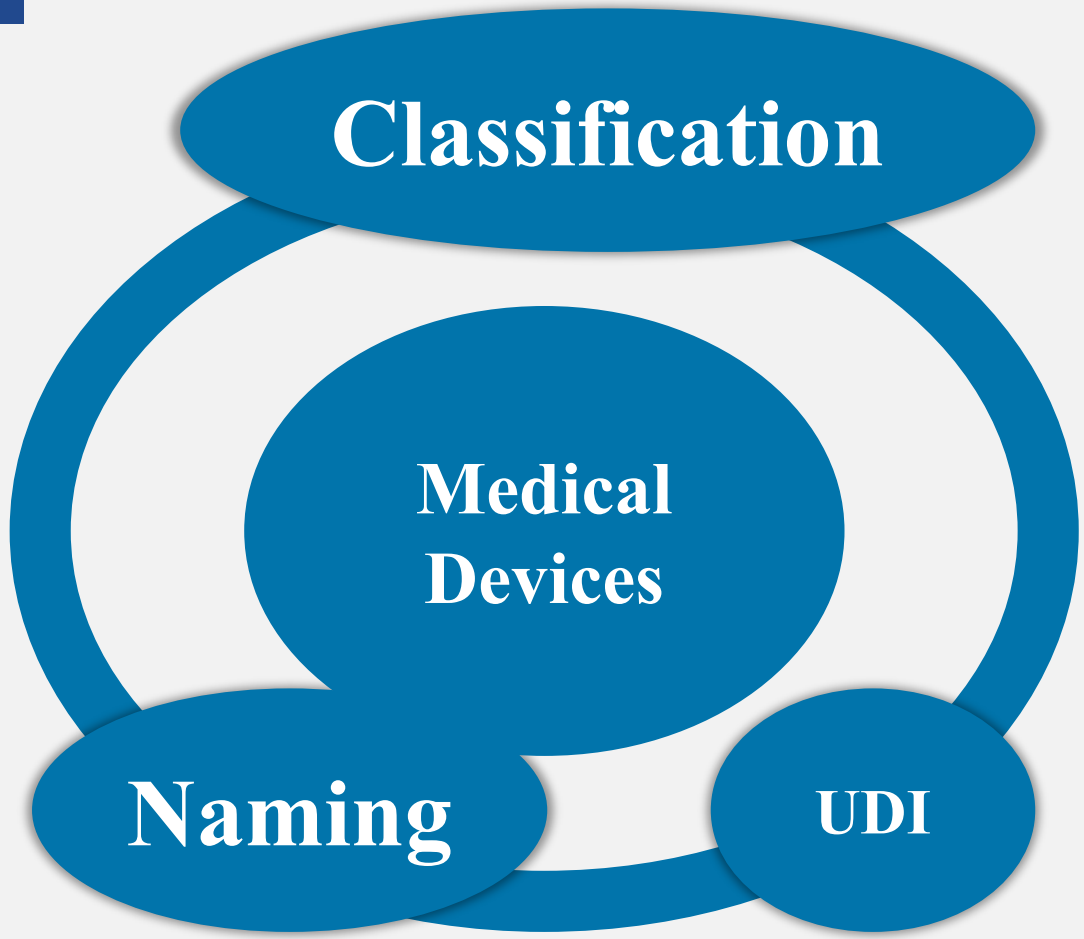
Pilot Program



PART 01

Policy Background

Needs for Refine Regulation of Medical Devices



Determination of Risk Management Categories of Medical Devices

Classification Rules + Catalog

Standardization on Naming Management of Medical Devices

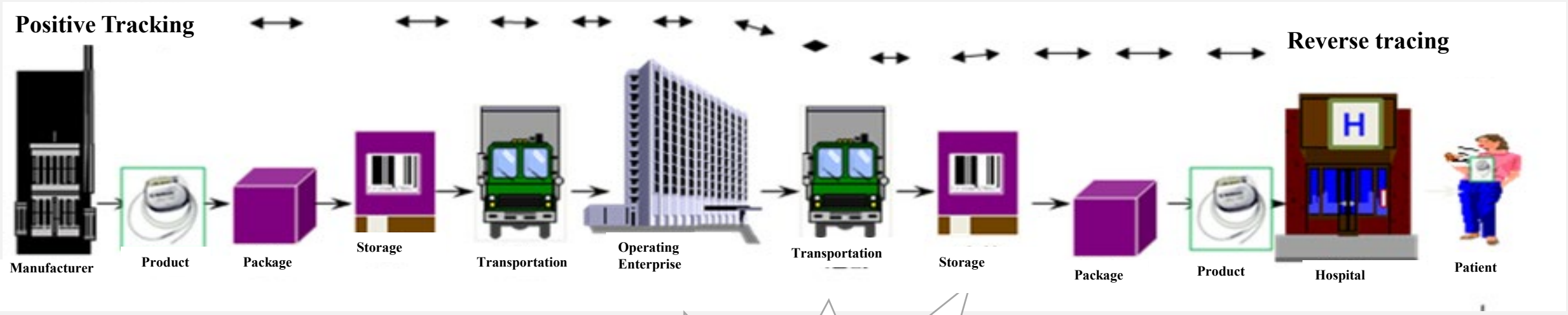
Naming Rules + Terms and Generic Name Database

Realization of Unified Recognition of Medical Devices

UDI Rules + Code, Carrier and Database

Classification						Naming	Registration Certificate	UDI
Category	Classification No.	Name	SN	Trade Name	SN	Generic Name	Registration Certificate	UDI
Ophthalmic instruments	16	Ophthalmic implants	07	Artificial lens	01	Posterior chamber artificial lens	GXZZ 20153221939 One-piece posterior chamber artificial lens	

Government Level - Needs for Lifecycle Management



Deeds of Department of Medicines Regulation:

Effective risk control

Adverse events monitoring, evaluation and warning

Urging of enterprise's accurate recall

Improvement of regulatory means and increasing regulatory efficiency

It is no mean feat for the traditional management means to accurately identify and trace devices in the first time.

Needs of Department of Health:

Accurate recognition of medical devices

Reduction of medical malpractices and increasing of service efficiency

Standardization on medical behaviors

Improvement of medical insurance level

The General Secretary of the CPC Central Committee, Xi Jinping addressed that medical device safety were the major livelihood and public security issues, proposed the requirements of the "Four Most" to strengthen the whole-process regulation of medical devices and put forth effort towards prevention of systemic and regional risks

Industry Common Demands

Manufacturers: device information tracing, AE monitoring and refine recall
Effective supply chain management (SCM) and logistics cargo control
Device re-evaluation, and consolidated brand protection plan

Circulation institutions: device accurate recognition and purchase-sale-stock informatization management

Using institutions: procurement management, device using management, settlement management and patient case binding

Patients: device identification, transparent consumption, protection of consumers' rights and clinical experience improvement

National Policy Level

General Office of the State Council	**Opinions on Accelerating Traceability System Construction of Important Products**	To accelerate the traceability system construction of food and drugs. Drugs: To accelerate the whole variety and whole process tracing of drugs, and establish and improve the traceability system of drugs.
The State Council	**The "13th Five-Year" National Plan for Drug Safety**	To formulate coding rules of medical devices and establish a coding system of medical devices
General Office of the State Council	**Deepening Reform of Medical and Health System 2019 Work Highlight**	To formulate the rules for UDI system and explore the cohesive application of standard coding of high-value medical consumables in the processes such as registration, procurement and usage
General Office of the State Council	**Reform Protocol for Governance of High-Value Medical Consumables (The 8th Central Comprehensively Deepening Reforms Commission)**	To formulate and issue the *Rules for Unique Device Identifier System*
The State Council	**Guiding Opinions of Strengthening and Standardizing Regulation During and After the Matter**	To establish and sound the traceability system based on the product coding management, for the important products such as food, drugs, medical devices and special equipment, to form an information chain of verifiable sources, traceable direction and accountable responsibilities.

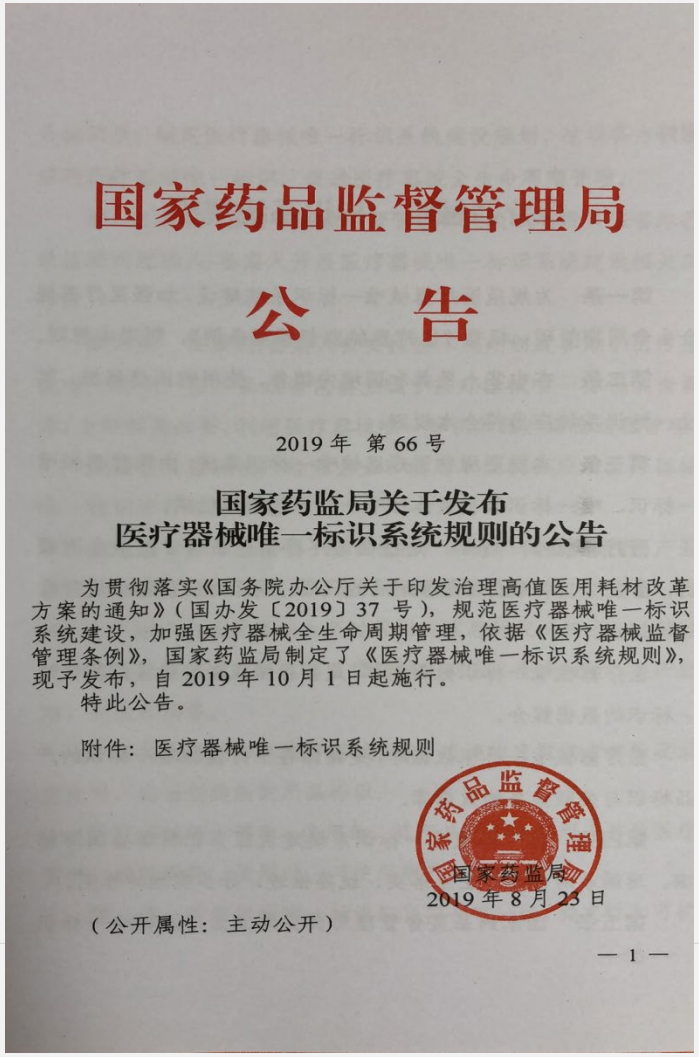
International Situation

IMDRF	UDI WG was set up in 2012 and IMDRF UDI guidance was issued in 2013; UDI Application Guide WG was set up in 2017 to carry out the international coordination from the implementation level, and was approved for release in March 2019, encompassing one technical document and two informative documents.
AHWP	UDI WG researched and formulated AHWP UDI White Paper in 2019.
United States	Rules for UDI were issued in 2013 and the first products were implemented in 2014. At present, the Class II above products are subject to UDI.
EU	Rules for medical devices and IVD were issued in 2017 to specify the UDI. MD Coordination WG was set up and the EUDAMED database covering pre- and post-market matters, including UDI module. It will be implemented in May 2020
Japan	The Ministry of Health and Welfare (MHW) issued a circular in 2008 (No. 0328001 of the Ministry of Health) requiring the bar code display of medical device products.
Korea	UDI regulations have been issued, and the first was implemented 2019.
Other countries and regions, such as Saudi Arabia, are successively advancing	

02 UDI Rule and Supporting Document

Rules for Unique Identifier System

- On August 23, 2019
- National Medical Products Administration (NMPA) printed and issued the No. 66 Announcement, 2019
- Rules for Unique Device Identification System



国家药品监督管理局

公　告

2019 年　第 66 号

国家药监局关于发布
医疗器械唯一标识系统规则的公告

为贯彻落实《国务院办公厅关于印发治理高值医用耗材改革方案的通知》（国办发〔2019〕37 号），规范医疗器械唯一标识系统建设，加强医疗器械全生命周期管理，依据《医疗器械监督管理条例》，国家药监局制定了《医疗器械唯一标识系统规则》，现予发布，自 2019 年 10 月 1 日起施行。

特此公告。

附件：医疗器械唯一标识系统规则

国家药监局
2019 年 8 月 23 日

（公开属性：主动公开）

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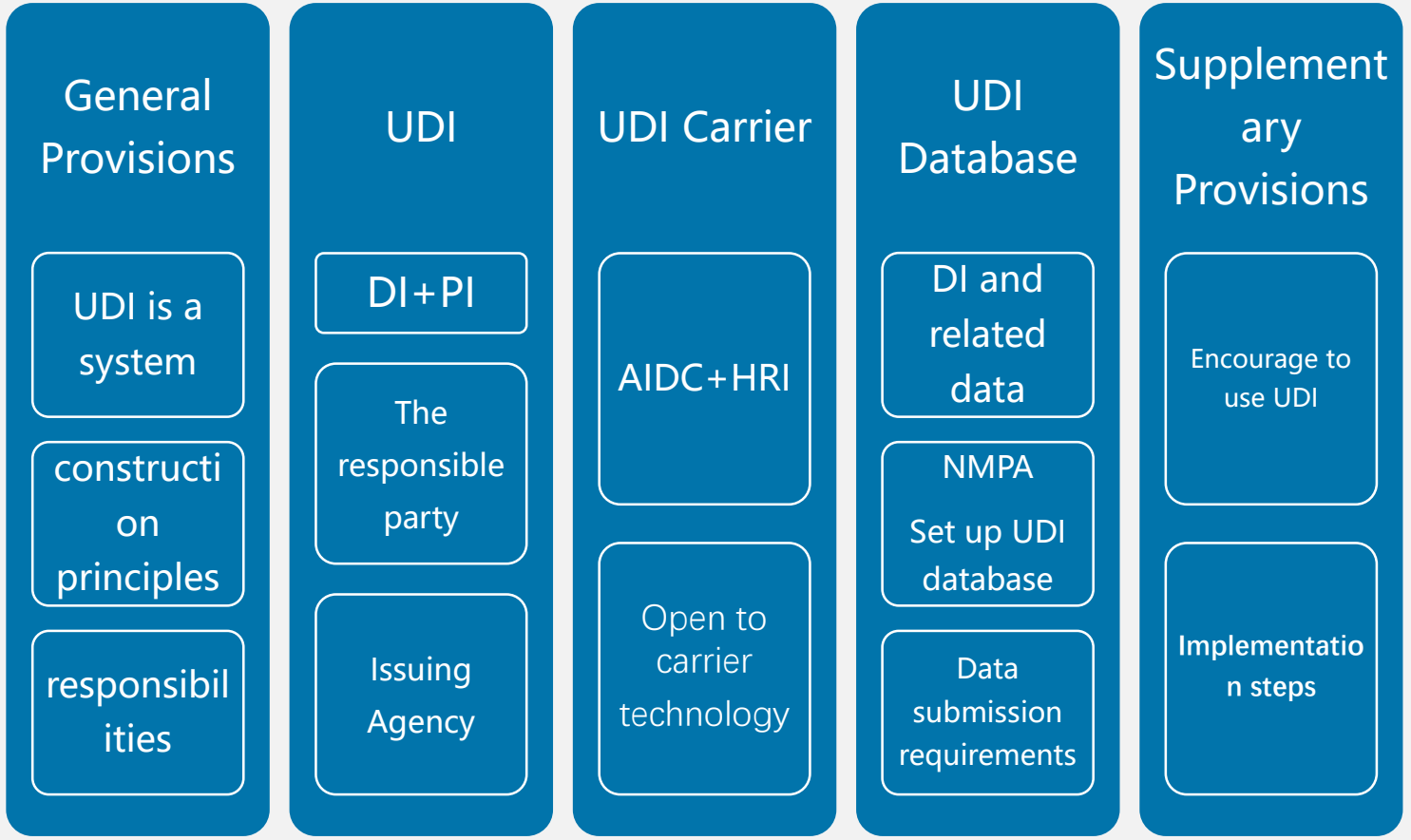
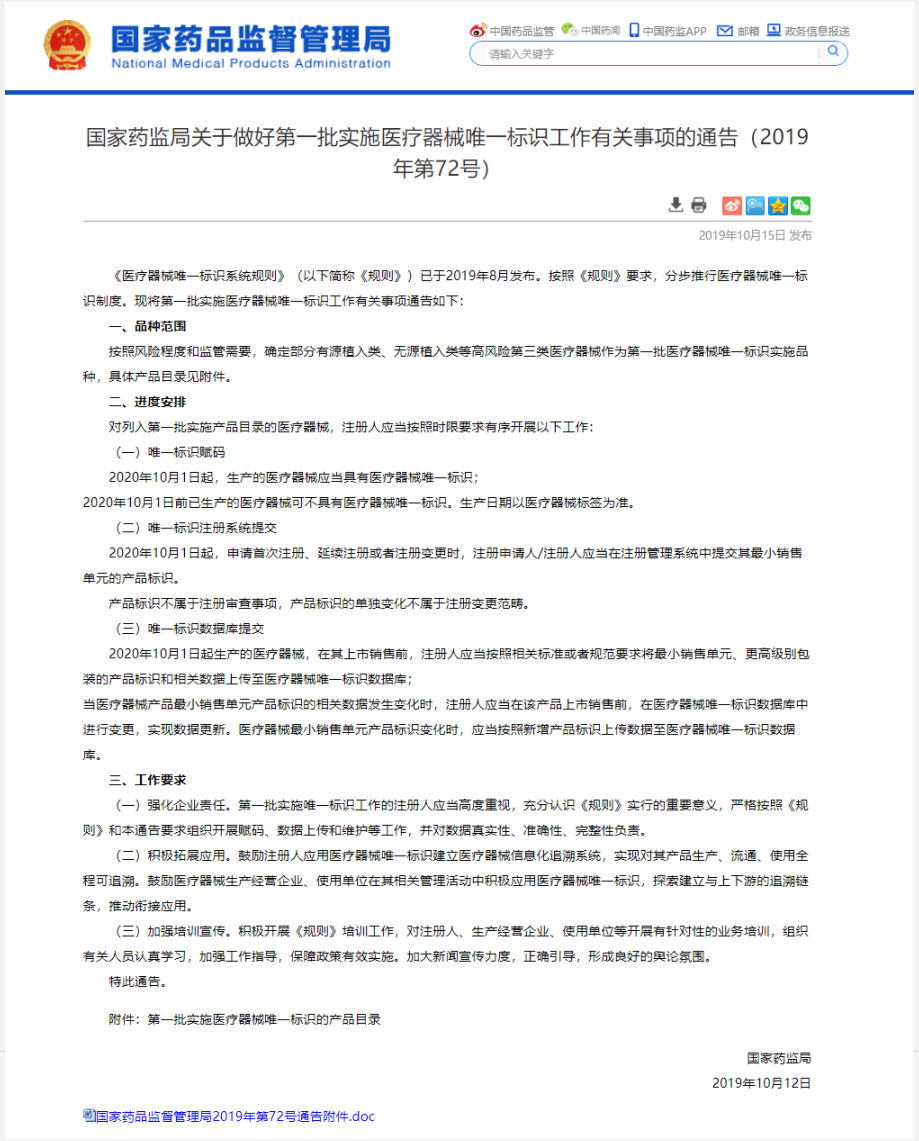
Content of the Final rule



Initial product to implement UDI



国家药品监督管理局
National Medical Products Administration

中国药品监管 中国药闻 中国药监APP 邮箱 政务信息报送
请输入关键字

国家药监局关于做好第一批实施医疗器械唯一标识工作有关事项的通告（2019年第72号）

2019年10月15日 发布

《医疗器械唯一标识系统规则》（以下简称《规则》）已于2019年8月发布。按照《规则》要求，分步推行医疗器械唯一标识制度。现将第一批实施医疗器械唯一标识工作有关事项通告如下：

一、品种范围

按照风险程度和监管需要，确定部分有源植入类、无源植入类等高风险第三类医疗器械作为第一批医疗器械唯一标识实施品种，具体产品目录见附件。

二、进度安排

对列入第一批实施产品目录的医疗器械，注册人应当按照时限要求有序开展以下工作：

（一）唯一标识赋码

2020年10月1日起，生产的医疗器械应当具有医疗器械唯一标识；

2020年10月1日前已生产的医疗器械可不具有医疗器械唯一标识。生产日期以医疗器械标签为准。

（二）唯一标识注册系统提交

2020年10月1日起，申请首次注册、延续注册或者注册变更时，注册申请人/注册人应当在注册管理系统中提交其最小销售单元的产品标识。

产品标识不属于注册审查事项，产品标识的单独变化不属于注册变更范畴。

（三）唯一标识数据库提交

2020年10月1日起生产的医疗器械，在其上市销售前，注册人应当按照相关标准或者规范要求将最小销售单元、更高级别包装的产品标识和相关数据上传至医疗器械唯一标识数据库；

当医疗器械产品最小销售单元产品标识的相关数据发生变化时，注册人应当在该产品上市销售前，在医疗器械唯一标识数据库中进行变更，实现数据更新。医疗器械最小销售单元产品标识变化时，应当按照新增产品标识上传数据至医疗器械唯一标识数据库。

三、工作要求

（一）强化企业责任。第一批实施唯一标识工作的注册人应当高度重视，充分认识《规则》实行的重要意义，严格按照《规则》和本通告要求组织开展赋码、数据上传和维护等工作，并对数据真实性、准确性、完整性负责。

（二）积极拓展应用。鼓励注册人应用医疗器械唯一标识建立医疗器械信息化追溯系统，实现对其产品生产、流通、使用全程可追溯。鼓励医疗器械生产经营企业、使用单位在其相关管理活动中积极应用医疗器械唯一标识，探索建立与上下游的追溯链条，推动衔接应用。

（三）加强培训宣传。积极开展《规则》培训工作，对注册人、生产经营企业、使用单位等开展有针对性的业务培训，组织有关人员认真学习，加强工作指导，保障政策有效实施。加大新闻宣传力度，正确引导，形成良好的舆论氛围。

特此通告。

附件：第一批实施医疗器械唯一标识的产品目录

国家药监局

2019年10月12日

国家药品监督管理局2019年第72号通告附件.doc

- 64 kinds of Class III products based on the Medical Device Classification Catalog
- Oct 1st 2020 implement UDI based on the Manufacture Date on the label
- Submit UDI-DI of Minimum Saleable Unit only
- Submit UDI-DI and related information of all package to the UDID

Highlights-Supporting Standards

Fundamental standards

- Fundamental requirement of unique device identifier YY/T 1630-2018
- Basic terms of unique device identification system YY/T 1681-2019

Information-based standards

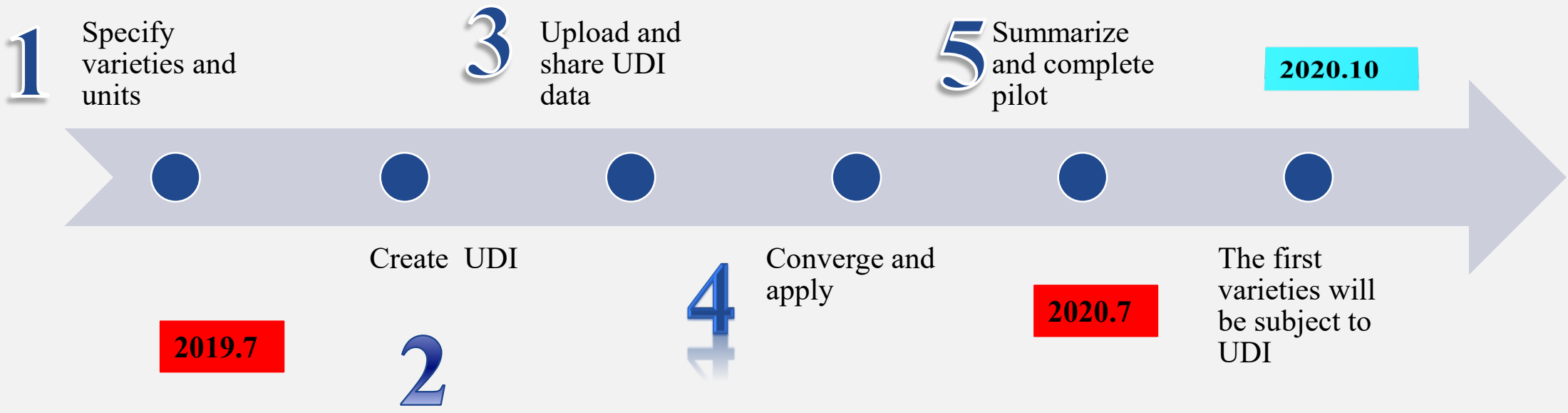
- UDID Data Filling Guidelines
- Basic Data Set of UDI system

03

Pilot Program

Overall Schedule of Pilot Program

✓On July 1, 2019, NMPA and the National Health Commission of the People's Republic of China co-printed and -issued a pilot program



Unique Identification Database

国家药品监督管理局 National Medical Products Administration 医疗器械唯一标识数据库

网站首页 | 政策法规 | 工作动态 | 在线咨询

输入搜索内容 搜索

详情结果： Divergence®前路颈椎融合系统（20643169339754） 打印

产品标识主DI基本信息

产品标识：	20643169339754	发码机构：	GS1	最小包装可使用单元数量：	4
产品名称：	Divergence®前路颈椎融合系统	规格：	G7743511	型 号：	G7743511
产品名称：	MEDTRONIC SOFAMOR DANEK，INC	统一社会信用代码：	G7743511	分类编码：	G7743511

产品标识主DI基本信息

器械是否为套件：	是	是否为药械组合产品：	否
是否为一次性使用：	是	最大重复使用次数：	1

包装标识信息：

包装标识	包装等级	包装内含小一级产品标识数量	包装内含小一级包装产品标识值
20643169339751	件	11	20643169339751
20643169339750	盒	11	20643169339754

Pilot Principles

I	II	III

• Important varieties
  • High-risk implants
• Extensibility
  • Typical products
	• (II) Multiple participation
	  • Whole link
	• Demonstration
	  • Whole chain
		• Timely summary
		  • Reproducible
		• Effectiveness
		  • Propagable

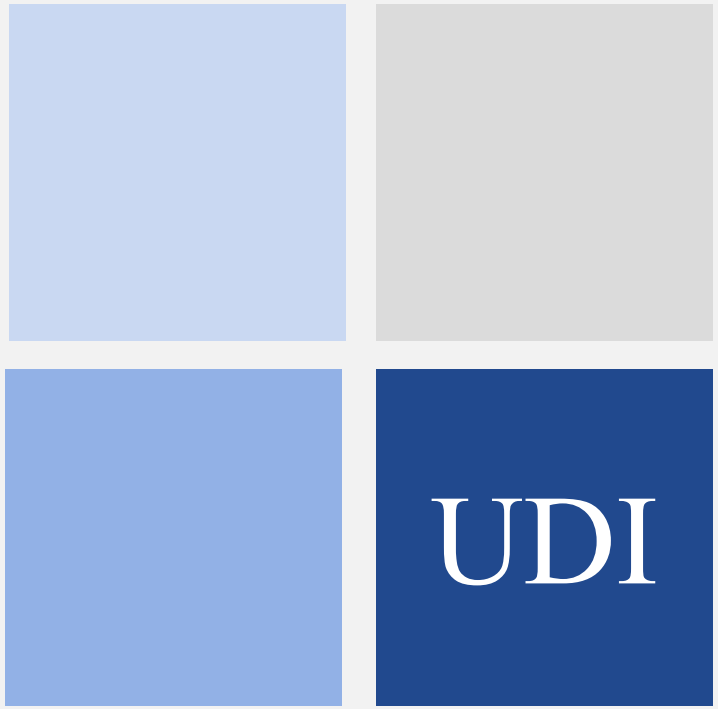
The First Pilot Units

16 provinces, municipalities and autonomous regions

108 Hospital

116 registrants, operating enterprises, etc.

A wide scope of implementation and an effective application is the “life force” of the UDI system International Languages, General-Purpose Languages and Specific Languages



Thanks for Listening!