Policy Brief – Regulations for the UDI System in China

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Summary

On 27 August 2019, the National Medical Products Administration (NMPA) published the **Regulations for the Unique Device Identifier (UDI) System for Medical Devices** (announced in Circular [2019] No. 66)[1]. Previously, there had been two public commenting rounds on draft versions in February 2018 and August 2018.

The regulations cover the different elements of the UDI-system, responsibilities of different actors, principles for issuing institutions and relevant requirements for registrants. Main changes to the previous drafts are the added requirements to apply UDI also on higher-level packaging (in Art. 12) and to upload UDI-DI to the registration management system when applying for registration / change registration (Art. 15). Additionally, the wording "market authorization holder" (上市许可持有人) was replaced by "registrant" (注册人/备案人).

The regulations enter into force on 1 October 2019, while actual implementation is to take place step-by-step based on risk classifications (specific steps still to be formulated). An accompanying interpretation published by NMPA[2] gives some background and further specifications e.g. on data sharing, on requirements for devices to be registered before and after 1 October, and on the choice of UDI data carrier.

At the same time, the UDI pilot implementation work moves forward (cf. work plan published on 8 July 2019). A kick-off meeting for industry participants was held by NMPA on 27 August 2019 in Beijing. Further details on the UDI pilot implementation published by NMPA include information on the set-up of a UDI task force[3], a list of participating companies[4], and a list of participating UDI users[5].

According to NMPA, further clarifications on the open questions, especially regarding the planned step-by-step implementation from 1 October onwards, are to follow in the coming weeks and months (to be jointly published by NMPA and the Center for Medical Device Evaluation, CMDE).

Main contents

The contents of the regulations cover the following areas:

General points (Art. 2-4)

- The regulations for the UDI system cover all medical devices sold and used within China;
- The UDI system consists of three elements, the Unique Device Identifier (UDI), the UDI carrier and the UDI database;

[1] http://www.nmpa.gov.cn/WS04/CL2138/357713.html
[2] http://www.nmpa.gov.cn/WS04/CL2201/357716.html
[3] http://www.nmpa.gov.cn/WS04/CL2197/357714.html
[4] http://www.nmpa.gov.cn/directory/web/WS04/images/uL28jIgo7q12tK7xfqyztPrzqjSu7HqyrbPtc2zytS149K9wcbG99C1xvPStS5kb2N4.docx
[5] http://www.nmpa.gov.cn/directory/web/WS04/images/uL28jEgo7q12tK7xfqyztPrzqjSu7HqyrbPtc2zytS148q508O1pc67LmRvY3g=.docx

- The use of international standards in the establishment of the UDI system is encouraged *[no mention of specific standards]*

Responsibilities of different actors (Art 5,6)

- NMPA is responsible for the establishment of the UDI system on a national level. Provincial Medical Product Administrations are responsible for guiding and supervising the implementation of UDI by registrants;
- MD registrants are responsible for applying UDI carriers (on products or packaging), uploading relevant data in the UDI database, and using UDI for lifecycle management;
- Manufacturers and users of MD are encouraged to actively incorporate and use UDI.

UDI specifications (Art. 7-9)

- The Unique Device Identifier consists of:
  - Device Identifier (UDI-DI), identifying registrant, model specification and packaging;
  - Production Identifier (UDI-PI), identifying information related to the production process. Depending on regulatory needs, this may include serial numbers, production batch numbers, production data, expiration date, etc.
- New identifiers shall be created in case of regulatory changes or changes to the product affecting identification or traceability. Identifiers of devices no longer sold or used shall not be re-used for other devices. When re-selling or re-using devices, the original identifier may be used.
- The Unique Device Identifier shall be unique, consistent (i.e. based on basic features of the products and only change when basic features change) and expandable (i.e. further develop according to regulatory requirements and new practical applications);
- Registrants shall create and maintain UDIs based on relevant UDI compilation standards. UDI compilation standards shall conform to the standards set by NMPA and by the UDI issuing agencies, which fit the criteria of these regulations. *[no further specifications in the document]*

UDI issuing agencies (Art. 10)

- UDI issuing institutions shall be legal entities in China, conforming to relevant requirements, e.g. on quality management and data security.
- UDI issuing institution shall:
  - provide registrants with the process of implementing its standards and guide their implementation;
  - upload coding requirements to the UDI database and dynamically maintain them;
  - each year before 31 January, submit a report to NMPA on UDIs created in the previous year.

UDI carrier (Art. 11, 12)

- AIDC and HIR carriers should be used. If space or applicability is limited, AIDC should be preferred;
- AIDC methods include 1D codes, 2D codes, RFID, etc.; it is encouraged to use advanced AIDC technologies;

- When using 1D codes, DI and PI can be provided in series or in parallel. When using RIFD, either a 1D or a 2D code shall be provided at the same time;
- The registrant shall select a suitable UDI carrier standard and, for devices marketed in their name, apply the UDI carrier on the smallest sales unit and the higher-level packaging or on the device itself; *[higher-level packaging as new requirements; unclear language about when UDI is to be applied on the device itself]*
- The registrant shall ensure that the UDI carrier is stably secured, clear and readable during the period of distribution and use.

UDI data / database (Art. 13, 14)

- NMPA formulates relevant standards and regulations for UDI data and coordinates the establishment of a UDI database - being open for public inquiry; *[database is to be open for queries from the public, as further specified in the accompanying interpretations published by NMPA]*
- Registrants shall upload, maintain and update relevant UDI data to the database according to relevant standards or regulations; *[cf. draft of standards for UDI basic data set and reporting guide]*
- Registrants are responsible for authenticity, accuracy and integrity of the data.

UDI and device registration (Art. 15)

- When applying for registration or change registration, registrants shall submit the UDI-DI in the registration management system. Registrants shall upload the UDI-DI and relevant data to the UDI database before the product is put on the market and sold.

Use of UDI-data (Art. 16)

- Medical product administrations may re-arrange and manage relevant data according to regulatory needs;
- Relevant parties are encouraged to adopt advanced information technology and apply UDI to manage production, distribution, use and other steps during the life cycle of medical devices.

Timeline (Art. 17)

- The regulations come into force on 1 October 2019. The specific steps for implementation based on classification shall be formulated and published separately. *[according to the wording in the accompanying interpretation (question 6), applications to the registration management system should include UDI from 1 October onwards; no information is available on the stated step-by-step implementation process; NMPA has stated to provide further clarifications on this point in the coming months]*

Preliminary assessment

The publication of the regulations for the UDI System has been highly anticipated. The changes since the last draft version are few. Yet, new requirements during registration, the short time until the date of entry into force and unclear language in the accompanying interpretation on these points leave many uncertainties regarding the specific steps for the implementation. According to NMPA, relevant clarifications will be published jointly with CMDE in the coming weeks and months.

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