Policy Brief – UDI pilot work plan China

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Background

On 3 July 2019, the General Office of the National Medical Products Administration (NMPA) and the General Office of the National Health Commission (NHC) published a notice about the **Pilot Work Plan for the Unique Device Identifier (UDI) System for Medical Devices** (Circular [2019] No. 56)[1] together with an announcement about the initiation of the UDI pilot work program[2].

Main contents

The purported objectives of the UDI pilot work are the following:

1) To establish a functional framework for the UDI system and data platform and to initiate a pilot UDI database;

2) To launch a pilot implementation of UDI during production, distribution, circulation and use of medical devices and formulate standards and specifications for pilot applications;

3) To explore UDI applications in adverse events reporting, recalls and traceability;

4) To explore UDI applications in health insurance as well as links to other systems, e.g. registration and approval, clinical trial application and medical insurance settlements.

The plan specifies that the pilot work will focus on high-risk (invasive) implants (e.g. heart implants, neural implants and prosthetics) as pilot products, aiming to cover typical products from a variety of types.

A wide variety of stakeholders is encouraged to participate in the pilot work. Aside from NHC, NMPA and relevant local-level authorities, this includes registration holders, distributors, users, academic associations and industry associations as well as institutions issuing identifiers. The plan also specifies which role participants from the different stakeholder groups will take in the pilot work.

A 5-stage implementation timeline is outlined in the pilot work plan:

1) In Stage 1 (Jul 2019), the focus will be on the set-up of the pilot work, including the determination of pilot product types and participants, the establishment of a coordinating work group, the organization trainings on the pilot implementation, and the formulation of implementation plans, concrete tasks and indicators by relevant participating units.

2) In Stage 2 (Aug-Nov 2019), questions regarding the creation and issuing of UDI will be addressed.

3) In Stage 3 (Dec 2019-Feb 2020), the focus will be on the UDI database, including standards for upload, download and interfaces.

4) In Stage 4 (Mar-Jun 2020), interdepartmental links and extended applications for UDI will be explored.

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[1] http://www.nmpa.gov.cn/WS04/CL2197/338683.html
[2] http://www.nmpa.gov.cn/WS04/CL2056/338684.html

5) The final Stage 5 (Jul 2020) will focus on evaluation and reporting on the results of the pilot work. Additionally, the implementation plan for the UDI implementation for the first batch of products will be finalized.

Preliminary assessment

Overall, the pilot work plan is seen as very ambitious covering a span of only one year, with many details left to being specified within Stage 1. Participating companies anticipate forming an initial evaluation after these details have been specified and first experiences have been made.

Additional uncertainties remain regarding the wider context of UDI implementation in China. Most importantly, the "Regulations for the UDI System for Medical Devices" (医疗器械唯一标识系统规则) have still not been published. So far, there have been two commenting rounds on draft versions in February 2018[3] and in August 2018[4].

Other recent developments include the completion of the tendering process on 2 July 2019 for the design of the UDI information management system, which was awarded to a yet unspecified company in Beijing for a bid of RMB 3.475 million[5]. Furthermore, on 3 July 2019 the National Institute for Food and Drug Control (NIFDC) disseminated the drafts for public comments of two standards on "Reporting Guide for UDI Database" and "Basic Data Set of UDI Database"[6]. The commenting period lasts until 4 September 2019.

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[3] http://samr.cfda.gov.cn/WS01/CL0779/225546.html
[4] http://www.nmpa.gov.cn/WS04/CL2102/329965.html
[5] http://www.mof.gov.cn/xinxi/zhongyangbiaoxun/zhongbiaogonggao/201907/t20190702_3289594.html
[6] https://www.nifdc.org.cn/nifdc/twowebsite/twoqxbzhglyjs/twoqxbzhzqyj/20190703150437.html