



Asian Harmonization Working Party
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CHALLENGES AND RECOMMENDATIONS FOR THE IMPLEMENTATION OF A GLOBALLY COORDINATED UDI SYSTEM

1. Foreword - International progress of UDI system for medical devices

GHTF UDI task force was formed in 2008, to establish and coordinate a unified medical device identifier system. Guiding documents were then issued in September 2011. After IMDRF was founded, it then took over the revision of the GHTF UDI file, and in September 2013 IMDRF UDI system guideline was released. The United States also issued UDI regulations in 2013, the EU MDR and IVDR released in 2017, also set up a dedicated chapter in the regulation for UDI and its implementation. Then in 2017, IMDRF established an UDI working group and released the UDI system application guidelines in March 2019 to further instruct the UDI guidelines released in 2013 years at the implementation level. South Korea, Saudi Arabia and other countries have also issued laws and regulations of UDI, and the global implementation of UDI is under progressing.

South Korea has established a UDI regulation and has the first set of products due for labeling in 2019. For Class 4 products the UDI labeling was required in July 2019 and the associated UDI data is due in October and must be entered in the UDI data base via a structured spread sheet. A risk based approach has

been established and the remaining risk classes have a staggered schedule with due dates through July 1, 2023.

Saudi Arabia has issued guidance on their UDI regulation and the due dates will commence 6 months after their UDI data base has been completed for Class D products. Subsequent products will be due over a three-year period.

Chinese Taipei has announced a guidance on "Medical Device UDI Practice" in October 2015 by referencing the U.S. FDA UDI Rule and IMDRF UDI Guidance. Although UDI labeling is being implemented as a voluntary requirement now, manufacturers are encouraged to print UDI labels and upload device identifier information to a domestic UDI database platform.

China launched the UDI system rule on August 2019. A risk-based strategy is used and the initial implementation product will be only part of the class III device. A one year pilot is employed to further test the system and the relevant parties are involved, such as manufacturer, distributor, healthcare provider, and regulatory authority.

2. Introduction

The purpose of the unique identification system for medical devices is to provide a coordinated and unified single system for the correct identification

of a specific medical device in the distribution and use of medical devices. The key is to understand that the benefits of UDI can only be realized if all parties involved, from manufacturers to medical institutions and patients, use UDI in their systems and throughout the entire supply chain. (IMDRF UDI guide 2013)

UDI system is an identification system for medical devices. Its purpose is to fully identify a specific medical device in distribution and use, rather than track and trace the medical devices. However, there is a connection between the two, because accurate identification of medical devices is the basis of tracking and tracing.

1972 U.S. Drug Listing Act, requested that the drug registration agencies provide the listing of drugs they manufactured to FDA, through the National Drug Code (NDC) via its three parts structure, which was identified by the FDA. Then in 2004, FDA issued the final rules, requiring some medicines contain machine readable bar code and include at least the content of the NDC, the American Pharmaceutical Supply Chain Security Act of 2013 requires a serial number on drug management, the European Union in 2011 issued Falsified Medicines Directive (FMD) to realize one drug one code requirements. On one hand, the unique identification of drug Falsified Medicines Directive needs to meet the requirements of continuous refinement, and on the other hand, the AIDC can realize the rapid and accurate acquisition of corresponding information.

For a long time, medical devices lack the uniform labeling of specifications, models and packaging levels. In 2004, when the US FDA adopted the drug barcode rule, it asked for public opinions on whether this regulation should be extended to medical devices. During its review, the FDA decided not to apply the barcode rule to medical devices, saying that such devices lack standards and a unique identification system like the drug national drug code system (ERG final report 2006).

For medical devices, the specifications at different package level uniquely identified to meet devices' daily clearing and product analysis of demand, the uniqueness of batch level identification can satisfy the demand of devices' quality management and recall, while in a single device level of uniquely identified will be used to track and trace of each piece of device, to improve supply chain security. If the ID can be direct to the serial number, it will greatly increase the risk of social cost especially for low risk medical devices, so the only logo should be per the practical application of medical device to meet the demand of the above three levels of recognition, to meet the different species and risk effective identification device at the same time have scalability to meet the future trend of serial number, ensure supply chain security. Like drugs, unique labels for medical devices should also be able to be expressed in the form of AIDC.

3. Unique identification of medical devices

The unique identification of medical devices refers to a series of Numbers or alphanumeric characters created through globally recognized device identification and coding standards. Through this mark, even for the medical devices not enter the market can be clearly identified. UDI includes UDI-DI and UDI-PI, where UDI-DI is a fixed part and can also be used as an "access key" to store information about UDID, while UDI-PI is a variable part to identify the production unit of the product. Per the identification requirements of the product, it can include serial number, production batch number, version number of medical device independent software, expiration date or production date.

The "unique" in the unique identification of medical devices does not mean the serial number management of medical devices. The unique identification of medical devices should be based on the identification requirements of the distribution and use of medical devices, which can meet the identification requirements of the distribution and use of medical devices at three levels: specification, model packaging, single batch of products and single products.

The unique labeling of medical devices is based on common international standards, and the regulatory authorities should encourage medical device manufacturers to select universally applicable coding standards, such as GS1,

HIBC, isbt-128, etc., and manufacturers to create unique labeling of medical devices per the rules of their code issuing institutions.

4. UDI data carrier

UDI carrier refers to the mode of carrying UDI, including automatic identification and data acquisition (machine reading) and manual reading (visual reading). The commonly used UDI data carriers include one-dimensional codes, QR codes and RFID. The IMDRF UDI guide states that the regulatory authorities shall not require specific AIDC methods, but the globally recognized AIDC methods are based on ISO standards adopted by global organizations (e.g., GS1, HIBCC or ICCBBA, etc.).

However, currently applicable data carriers should be considered when formulating regulations. For example, it is recommended to have one-dimensional codes or QR codes when using RFID, because the reading equipment of RFID is not popular at present.

The general requirement for carriers is that medical devices can be recognized before use. For example, implantable medical devices can be recognized by binding UDI information with patient information, thus eliminating the need for direct part identification. For reusable devices that need to be reprocessed between each use, the original packaging will be lost after sterilization, and

the it will be need to be marked directly. In the case of space limitation, the priority of AIDC and HRI and possible exemptions should be clarified.

5. UDI database of medical devices

Medical device a unique identifier databased is a static database, database includes only the UDI - the basic attributes of DI, not including production flow and the specific identification information for production, medical devices' unique identification should be set up by the regulatory agencies responsible for database and open to the public, the manufacturer is responsible for the upload and update the information, regulators should establishing database of medical device unique identification by referencing the core fields of the IMDRF UDI system guide; A unique identifier database medical device shall not contain business confidential information of the product.

6. Responsibilities of the parties

The successful implementation of a unique identification system for medical devices requires a clear understanding of each party's responsibilities.

Regulatory authorities: formulate regulations for unique device identification system of medical devices based on the basic framework of IMDRF UDI guidelines; Based on internationally accepted standards, recognition (or other

appropriate means) of code issuers, the recognition should consider the coding standards currently available in the market; Establish the database of unique identification system for medical devices.

1) Medical device manufacturer: responsible for creating the unique mark of medical device per the standard of issuing institution; It is responsible for placing the unique identification of medical devices on the label of the device or on the device itself, and on all higher levels of device packaging.

Responsible for uploading product identification and related information to the unique identification database of medical devices, and maintaining and updating.

2) Distributors and users of medical devices: actively use the UDI compliance devices to carry out related management.

3) Code issuing agency: formulate UDI rules in accordance with relevant international standards, and provide guidance to manufacturers in the creation of unique identification, selection of carrier and granting.

4) Industry Association: actively collect the problems of the industry in the formulation and implementation of UDI regulations, and make a good link between the government and manufacturers.

7. Challenges in the implementation of UDI and suggested ways to cope with them

Although IMDRF issued UDI system guidance as early as 2013, there are still many problems in the implementation of UDI system in various countries.

Here are the challenges faced in the implementation of UDI and the proposed ways to deal with them.

1) the diversity of the device can give a UDI system has caused great difficulties, the implementation of national laws and regulations are usually only includes the basic requirements of implementing UDI system, industry need more guidance on the level of implementation, for implantable medical devices, the IVD instrument set, IVD products, apparatus of medical equipment system, Stand-alone software such as medical devices, should develop more specific detailed rules for the implementation, to guide the industry's compliance.

2) for some specific medical devices, such as orthopedic surgery trays and soft contact lenses, great difficulties have been encountered in countries that have implemented UDI, and all stakeholders should jointly search for appropriate solutions on a global scale.

3) the quality of data is a huge challenge in the implementation of UDI system.

Through adopting standard UDI fields and restricting free text in the design of UDI database, data quality will be improved to some extent. However, it is necessary to adopt appropriate ways or procedures to verify the contents in the database, supervise all parties and rule by society.

4) inconsistent trigger conditions for the generation of new UDI-DI may make the UDI system unable to achieve the expected effect among different countries. Although the IMDRF UDI guide lists the pre-requisite to assign new UDI-DI for the change of data elements in UDID, and gives manufacturers a certain degree of guidance and flexibility, there may be differences in the implementation of different countries or manufacturers. This has become the hotspot of international UDI research.

5) specific requirements of users. Since the IMDRF UDI guidelines and UDI regulations of various countries and regions are only the minimum requirements for the establishment of UDI system, in the complex distribution chain and use environment of medical devices, some relevant parties may raise higher requirements than the IMDRF UDI guidelines or regulations. It need to be highlighted that only if all involved parities (from the manufacturers to the medical institutions and patients) are using UDI in their workflow, then the benefit of UDI can be reflected; if the related parties do not take the initiative

to record UDI, UDI system not only can't achieve our goals, but it may request additional identification would eventually greatly increase the social cost of UDI implementation. To avoid this kind of circumstance from happening, on the one hand, we need the regulators reduce specific demand during regulation drafting and implementation as much as possible; and on the other hand, manufacturers need to understand the UDI as early as possible to implement the UDI in target area for distribution and use, by means of international coordination, be prepared ahead of time.

6) manufacturers still face difficult problem of compliance, recommended regulators to adopt, in accordance with the risk level of the device, then gradually implemented in stages; if possible, before the implementation, a pilot is necessary to carry out. The first stage of UDI system implementation usually be set within two years after the release of UDI regulation. Then there would be 2 years interim for every other device classes (according to the size of the industry of the area and the actual situation, can be appropriately reduced to 1 year), for a medical device with DPM (direct part marking) its implementation date usually will be two years after the date of compliance.

7) Related stakeholders lack enough understanding for the UDI system, the core of the successful implementation of UDI system is all stakeholder' s involvement and understanding. Although regulators in the formulation of regulations typically interact with the industry, and is establishing the UDI help

desk, release guidance documents, carrying out the relevant pilot and training, etc., but in the whole ecosystem of UDI, participants are not only regulators, , all parties 'active participate and form a good atmosphere is the key to a successful UDI implementation.

8. Best practices for global coordination of UDI

Due to the different regulatory and industrial environment in different countries and the participation from multiple stakeholders, it is not easy to coordinate the UDI system of medical devices globally. The implementation of UDI system is a long and arduous process. UDI system is the product of all parties' compromise.

When making decisions, it is suggested to place UDI system in the context of a full life cycle management consideration of medical devices. It will be more conducive for a harmonious situation than only from several stakeholders 'own perspective.

In addition, it is beneficial to have a correct understanding of the purpose and significance of UDI.

UDI system is an adequate identification system for devices in the process of distribution and use. It is more conducive to the formation of consensus to

focus on the identification needs of specific medical devices of all parties.

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Reference:

1. IMDRF/UDI WG/N7:2013 UDI Guidance Unique Device Identification (UDI) of Medical Devices
2. IMDRF/UDI WG/N48: 2019 Unique Device Identification system (UDI system) Application Guide