The 24th AHWP Annual Meeting

Chinese Taipei's Experience in Implementation of UDI and Lessons Learned & Benefits Realized from UDI Adoption

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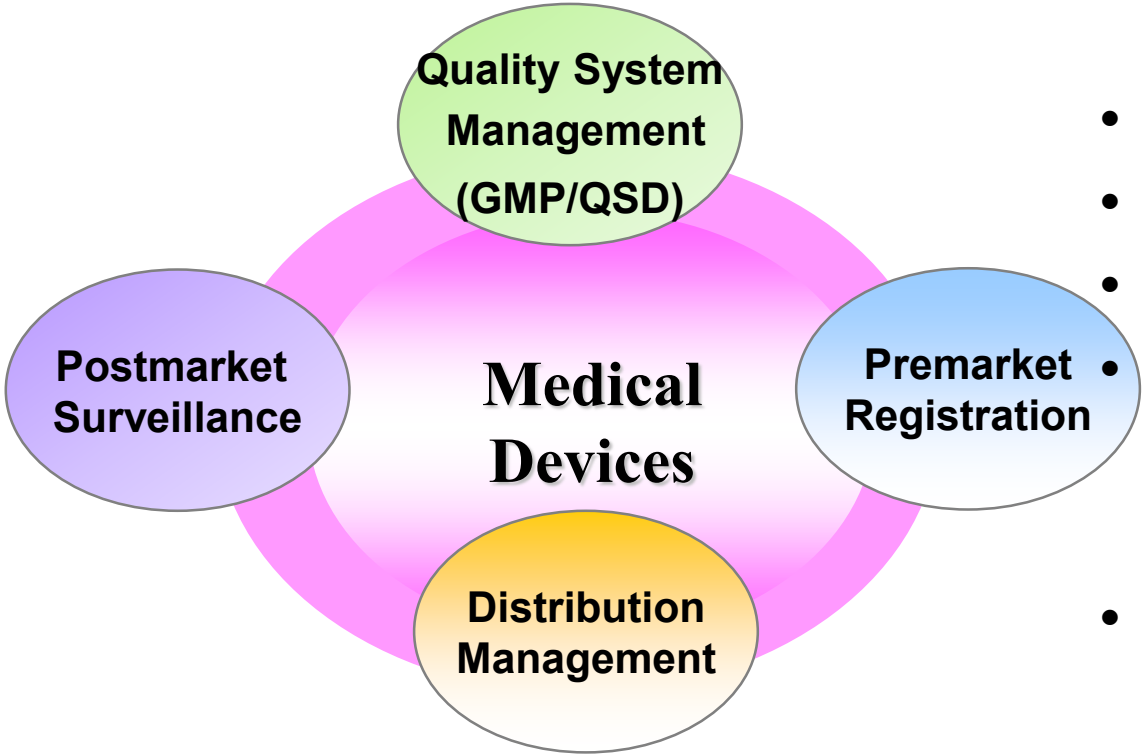
Muscat, Sultanate of Oman

Outline

- Medical device regulatory framework
- UDI regulation update
- Future planning
- Application by hospitals

Medical Device Regulatory Framework

Medical Device Regulatory Framework



- Beginning of registration: 1973
- GMP implementation: 1999
- Reclassification: 2000
- No. of registered MD licenses: 46,942 (as of Sept. 2019) (75% Imported; 25% Domestic)
- No. of registered MD manufac-turers: 1,582 (as of 2018)

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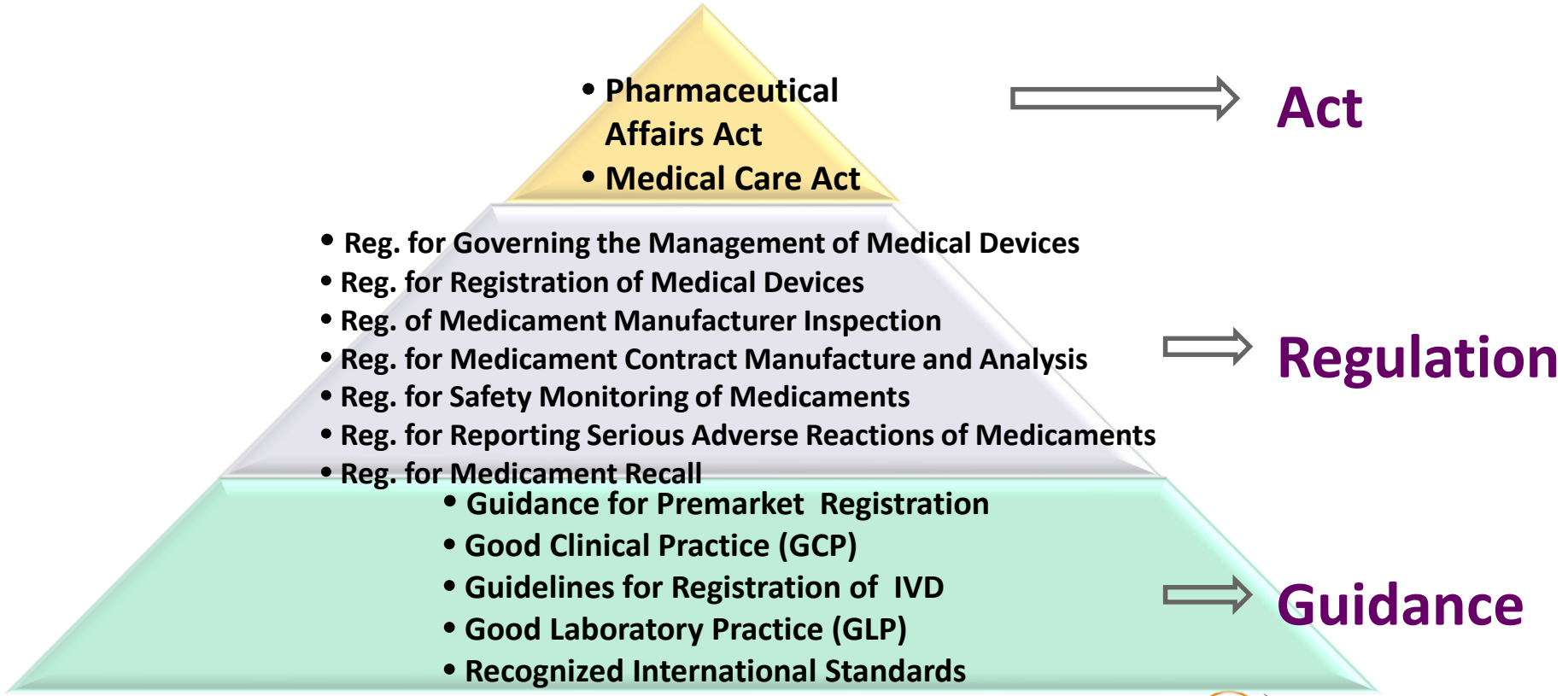
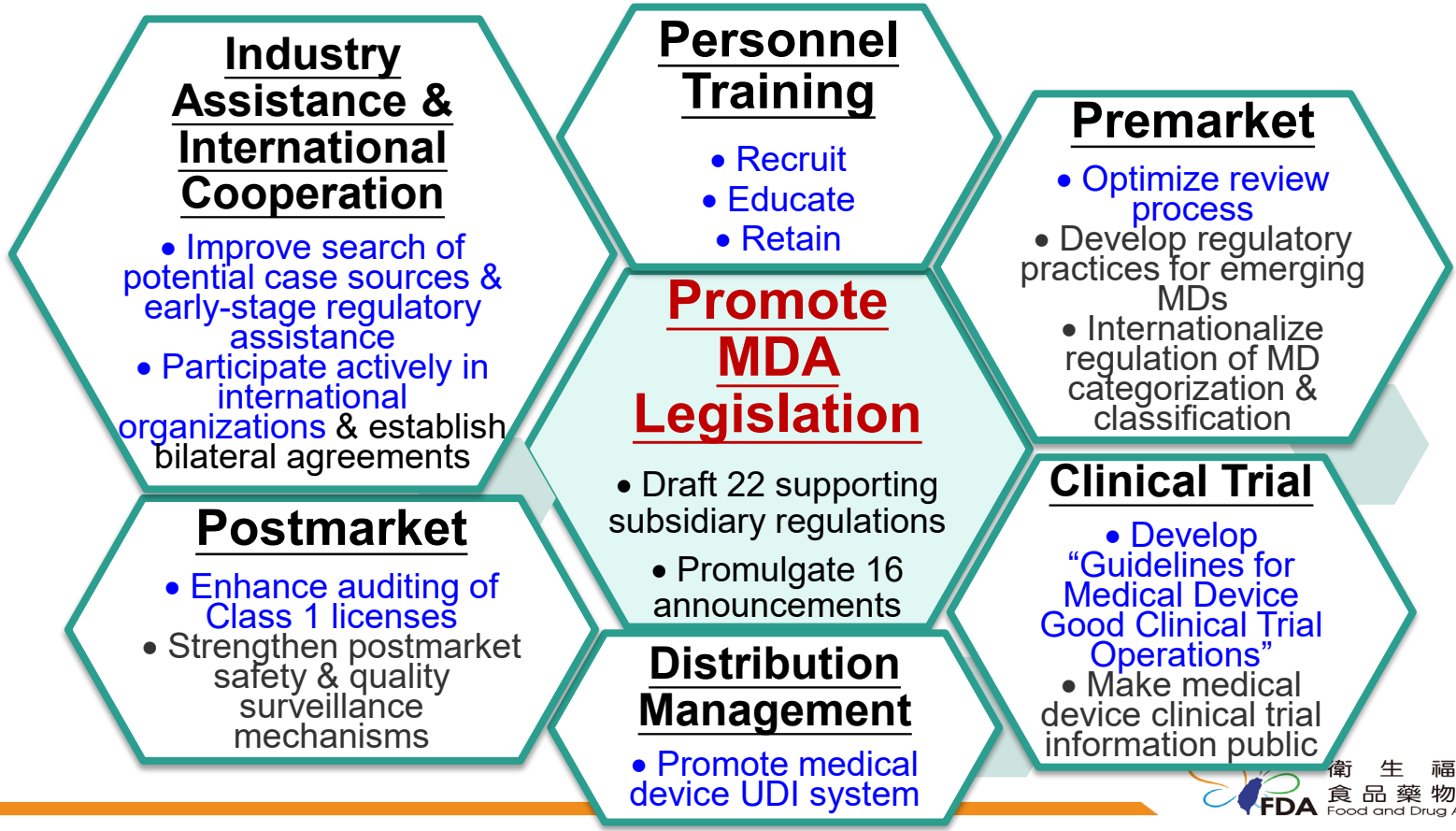
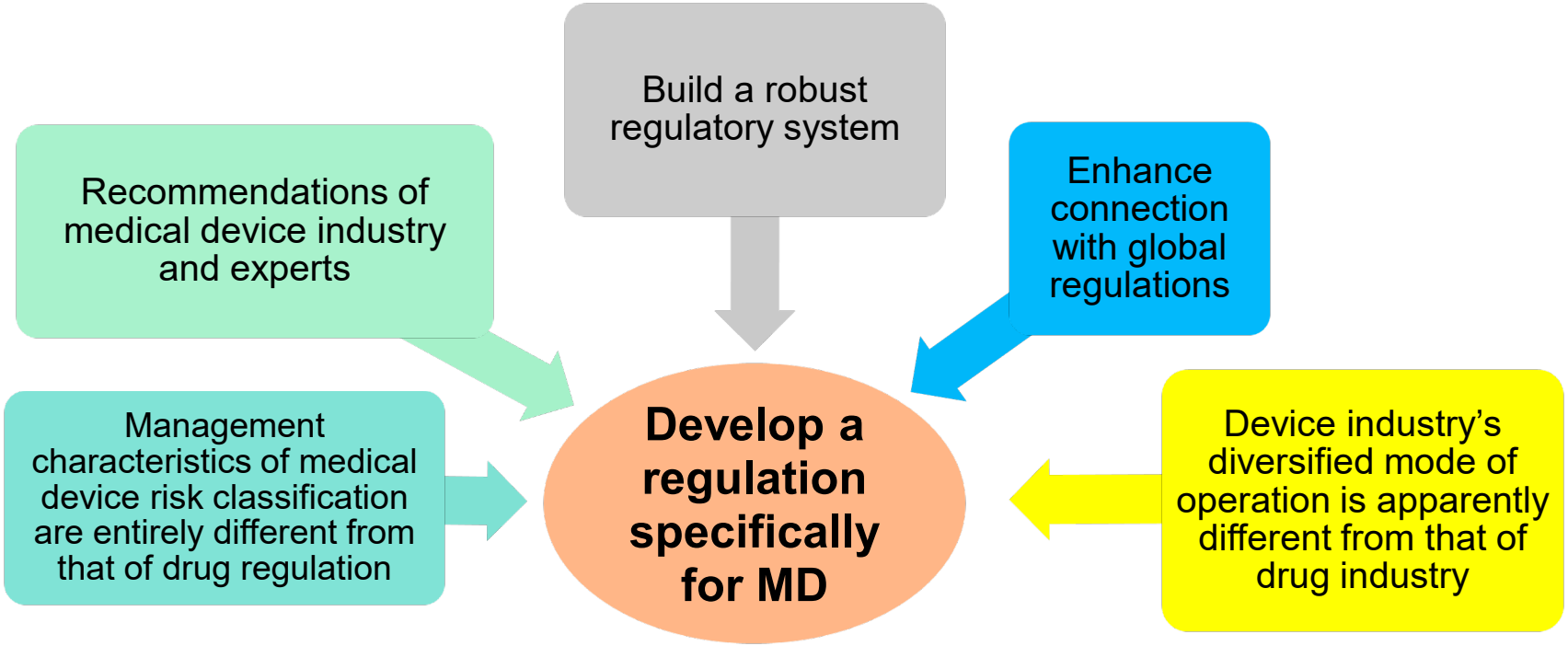
Basis of Medical Device Regulation



Key Points of Policy Administration



Reasons for Promoting Medical Devices Act



P.S. The draft of MDA is currently being examined in Legislative Yuan.

Benefits of Legislating Medical Devices Act (MDA)

- A global regulatory trend is for any jurisdiction to have one independent law of medical devices.
- MDA is formulated by **using relevant articles on medical devices in Pharmaceutical Affairs Act as the basis**, and by gathering legislative references on medical device specific laws that have been established internationally, e.g., **EU, ASEAN, China & Korea**.

- Regulatory mechanisms in MDA are established **according to product lifecycle and risk management principles** for time-to-market acceleration and patient benefits.
- MDA complies with government-initiated "5 plus 2 Biomedical Industry Innovation Program" & emphasizes the **developmental needs of academic, research, and (repair) industry sectors** for enhancing international competitiveness of industry.

- **One set of regulations for comprehensive management: Using MDA as a single legislative source to establish overall planning of medical device regulatory system** & recognizing characteristics of the diversity in medical devices and industry to **develop related and supporting subsidiary regulations accordingly**.

UDI Regulation Update

Progress in UDI Advancement (1/2)

- The Pharmaceutical Affairs Act contains an article to request UDI labeling.
- At the moment, UDI is promoted through a contracted project.

2013
2014

1. Maintain a firm grasp of international regulations and trends of UDI
2. Seek to understand the general situation and needs for introducing UDI domestically
3. Pilot and promote UDI introduction in hospitals

2015
2016
2017

1. Announce domestic UDI practice
2. Establish a domestic UDI Database (TUDID) information management platform
3. Continue to follow up user end (hospitals) and provide hospitals with pilot modules as reference

Progress in UDI Advancement (2/2)

- 2018
- 2019

1. Continue to follow up on relevant international UDI practices and current implementation status
2. Assist domestic manufacturers and importers in introducing UDI.
3. Encourage license holders of high-risk medical devices to upload device identifier information to the TUDID platform
4. Enhance functions of TUDID platform and provide user-friendly interface
5. Publish operating manual and FAQs of TUDID platform for reference by the industry
6. Hold related seminars, meetings, and training courses to collect relevant comments from the industry and medical institutions

Recent UDI Promotion Activities

- UDI Seminar in Taipei

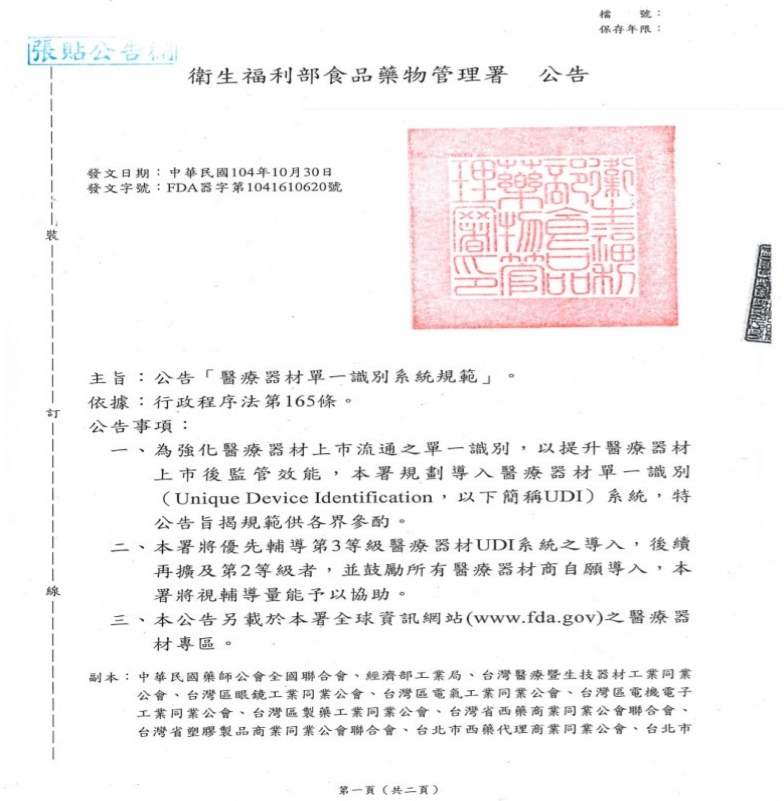
- UDI Training Workshop

- UDI Seminar in Taichung

- UDI Expert Consensus Meeting

Medical Device UDI Practice

- “Medical Device UDI Practice” announced on 30 October 2015
- Detailed rules on:
  - ✓ definition of terms
  - ✓ labeling method
  - ✓ package labeling requirement
  - ✓ carrier types for labeling
  - ✓ date format for package labeling
  - ✓ usage of unique identification code and its barcode
  - ✓ data elements of UDI information platform
  - ✓ targeted groups of labeling implementation
- Devices not applicable for compliance enumerated
- Content re-evaluated in 2019 to keep up with global implementation status and domestic development



檔　號：
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張貼公告欄

衛生福利部食品藥物管理署　公告

發文日期：中華民國104年10月30日
發文字號：FDA器字第1041610620號

裝

主旨：公告「醫療器材單一識別系統規範」。

依據：行政程序法第165條。

訂

公告事項：

一、為強化醫療器材上市流通之單一識別，以提升醫療器材上市後監管效能，本署規劃導入醫療器材單一識別（Unique Device Identification，以下簡稱UDI）系統，特公告旨揭規範供各界參酌。

二、本署將優先輔導第3等級醫療器材UDI系統之導入，後續再擴及第2等級者，並鼓勵所有醫療器材商自願導入，本署將視輔導量能予以協助。

線

三、本公告另載於本署全球資訊網站(www.fda.gov)之醫療器材專區。

副本：中華民國藥師公會全國聯合會、經濟部工業局、台灣醫療暨生技器材工業同業公會、台灣區眼鏡工業同業公會、台灣區電氣工業同業公會、台灣區電機電子工業同業公會、台灣區製藥工業同業公會、台灣省西藥商業同業公會聯合會、台灣省塑膠製品商業同業公會聯合會、台北市西藥代理商業同業公會、台北市

第一頁（共二頁）

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Current Implementation Status

- Mandatory UDI labeling requirement has not yet been incorporated into regulation at the moment.
- Manufacturers are being encouraged to print UDI labels and upload device identifier information to the TUDID platform.
- Continuous devotion of attention to global trends in UDI is being given.
- Planning is underway to modify the current UDI practice according to IMDRF guideline of 2019.

Fundamental Elements of a Harmonized UDI System

In accordance with IMDRF/UDI WG/N48 FINAL:2019

1. Development of a standardized system of Unique Device Identifiers (UDIs)
2. Placement of UDIs in human readable and AIDC formats/forms on package labels and in some cases, on the device itself
3. Submission of core UDI data elements to a UDID
4. Setting of appropriate transitional and implementation arrangements to ensure a smooth UDI system implementation

Strategy according to IMDRF Guideline

Recommendation from IMDRF:

1. Develop a standardized system of identifiers
2. Placement of UDIs in two formats on labels
3. Build UDI data elements to a UDI database
4. Set appropriate transitional and implementation arrangements

Corresponding Solution:

1. Define the standardized format in the UDI practice
2. Need to amend regulations for mandatory implementation
3. Need to establish a database for information uploading
4. Need to pay attention to international trends and provide adequate assistance to the industry

UDI Implementation Plan in Chinese Taipei

- Labeling

  Certain classes of medical devices must have mandatory labeling of UDI.
- Device Identifier (DI) information uploading

  Any license owner with the announced medical devices shall, before putting them on the market for sale, upload their UDI and corresponding product information to the system (Taiwan UDI Database or TUDID) designated by the central competent authority.
- Application aspect
  - DI is regarded as part of the information for declaring data on source tracing and flow tracking and will replace product license number, catalogue number, etc.
  - UDI is to be incorporated into part of the recorded information of distribution source in order to facilitate the voluntary development of electronic linkage control tools for device distribution.

Realization of UDI by Medical Devices Act (1/2)

- **Mandatory labeling**

Article 33 (**Subparagraph 10** of Paragraph 1)

- Medical device firms shall indicate the following particulars on the labels, instructions, or packaging of medical devices, as approved, registered and approved, or listed in accordance with Paragraph 2 of Article 13 and Paragraph 1 of Article 25. However, this shall not apply to those exempt from such indication, as announced by the central competent authority: …; **10. Other particulars that shall be indicated, as announced by the central competent authority.**

According to this draft article, UDI can be one of the announced mandatory items to be placed on the label.

Realization of UDI by Medical Devices Act (2/2)

- **Information used to record the product flow**

Article 19
(**Paragraph 3**)

- For medical devices of certain risk class per public announcement by the competent authority, medical device firms and medical affairs institutions shall establish and maintain data on direct supply sources and flow of products.
- Product items per public announcement by the competent authority shall have data established and maintained in the preceding paragraph declared to the competent authority.
- **Regulations governing the scope, methods for establishment and maintenance of data, contents and methods of declaration set forth in the preceding two paragraphs, as well as other matters to be complied with shall be established by the central competent authority.**

This draft article authorizes competent authority to announce the device scope, methods for establishment & maintenance, as well as other matters to be complied with (sets the legal basis).

Proposed Schedule for Mandatory Implementation

In phase with EU's schedule for mandatory labeling of UDI:

- Phase I

  1 June 2021 for Class 3 medical devices (not including In Vitro Diagnostics)

- Phase II

  1 June 2023 for Class 3 IVDs and Class 2 medical devices

- Depending on the implementation situation of the above mentioned phases, there would be rolling adjustment in the UDI labeling schedule for other medical devices.

Taiwan UDI Database (TUDID)

http://udid.fda.gov.tw

Taiwan UDI Database (TUDID) Fields

There are 16 elements in total with 65 data fields, out of which 23 are required data fields (marked with *).

Data Entry for TUDID Fields

Data fields are grouped into 16 elements:	
Device Registration Information (TFDA Registered License Number, Brand Name, Device Class, Device Category)	**Global Medical Device Nomenclature** (GMDN)
Device License Information(Validity Period, Country of Origin)	**Product Characteristics** (e.g., Single Use? Reuse?)
Device Identifier (DI) Information (Issuing Agency, Primary DI Number, Catalogue Number, Product Description)	**Production Identifier (PI) Information on Labeling** (Lot Number Availability, Serial Number)
Product Circulation Information (Last Date of Circulation)	**Warning Information** (Containing DEHP?)
Package Level DI Information	**Clinical Size**(Size Type, Size Value, Unit of Measure)
Manufacturer Contact Information	**Storage & Handling Information**
Product Status (Kit? Combination Product?)	**Sterilization Method** (Packaged Sterile? Sterilization Prior to Use?)
U.S. FDA Regulatory Information	**NHI Reimbursement Information**

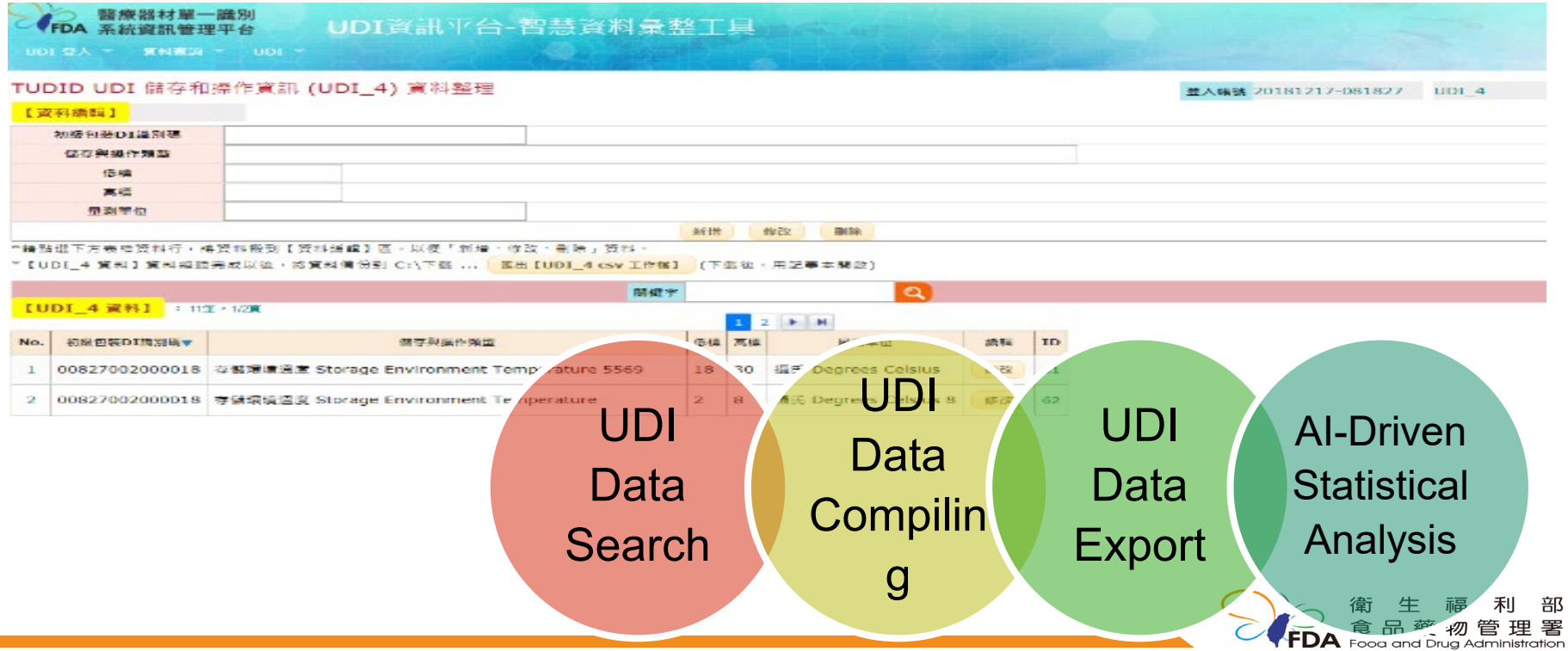
Required Data Fields for TUDID

23 of 65 data fields are required:

1	License Number	13	Serial Number
2	License Number (Type)	14	Validity Period / Shelf-Life
3	UDI Issuing Agency	15	Device required to be labeled as containing natural rubber latex or dry natural rubber
4	DI for Base Package	16	Whether the device contains DEHP
5	Quantity per Package	17	Size Type
6	Catalogue Number	18	Size Value
7	Manufacturer Contact Number	19	Unit of Measure
8	Manufacturer Email	20	Other Size Type
9	Single-Use Medical Device	21	Packaged as Sterile
10	Restriction on Reuse	22	Requires Sterilization Prior to Use
11	Lot Number	23	Sterilization Method
12	Manufacturing Date		

UDI Data Compilation Tool

- For use before uploading data into TUDID
- Automated check for errors in data format



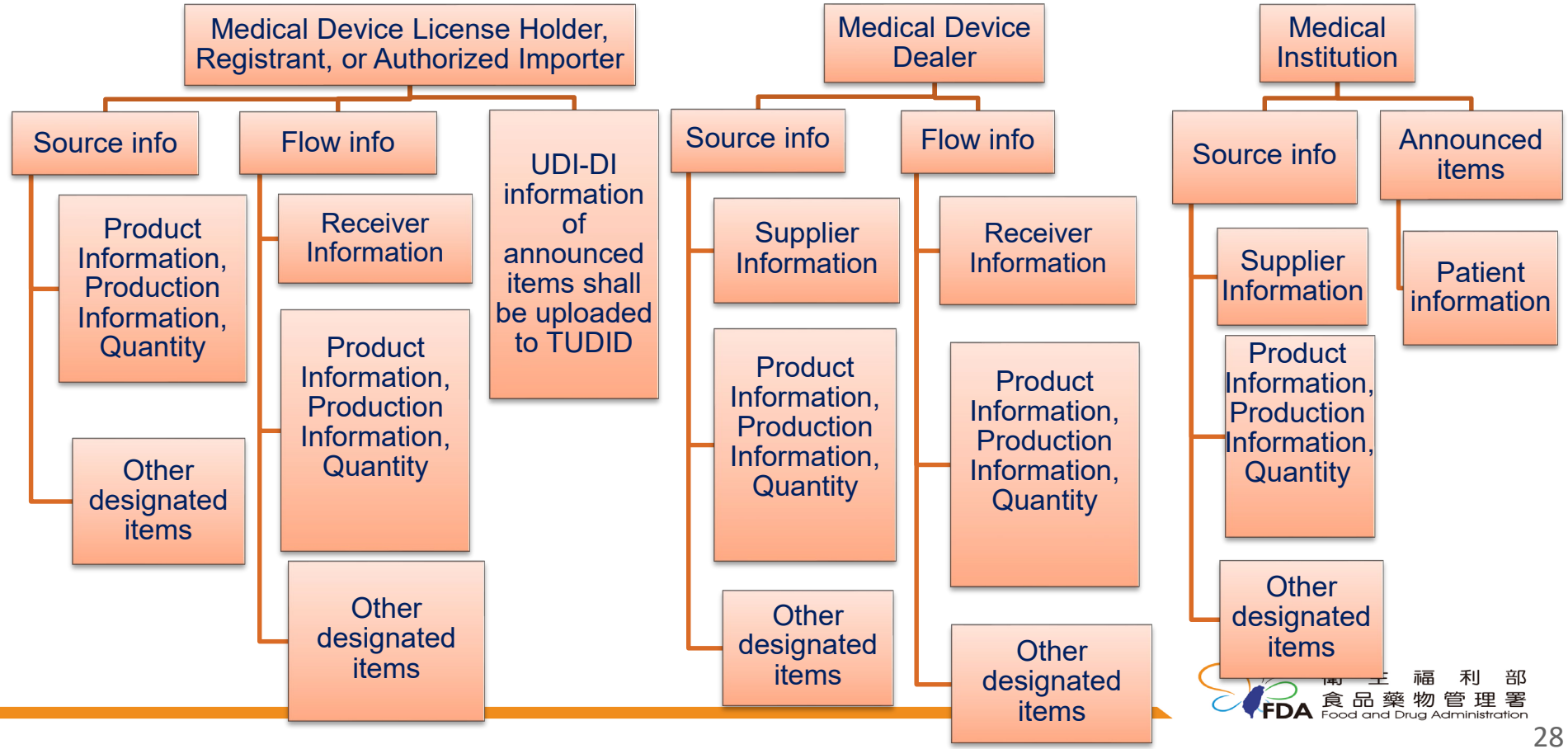
UDI Help Desk

- Web-based query system for comments and feedback

- Consultation phone line also available

Future Planning

Tentative Planning on Product Tracing and Tracking



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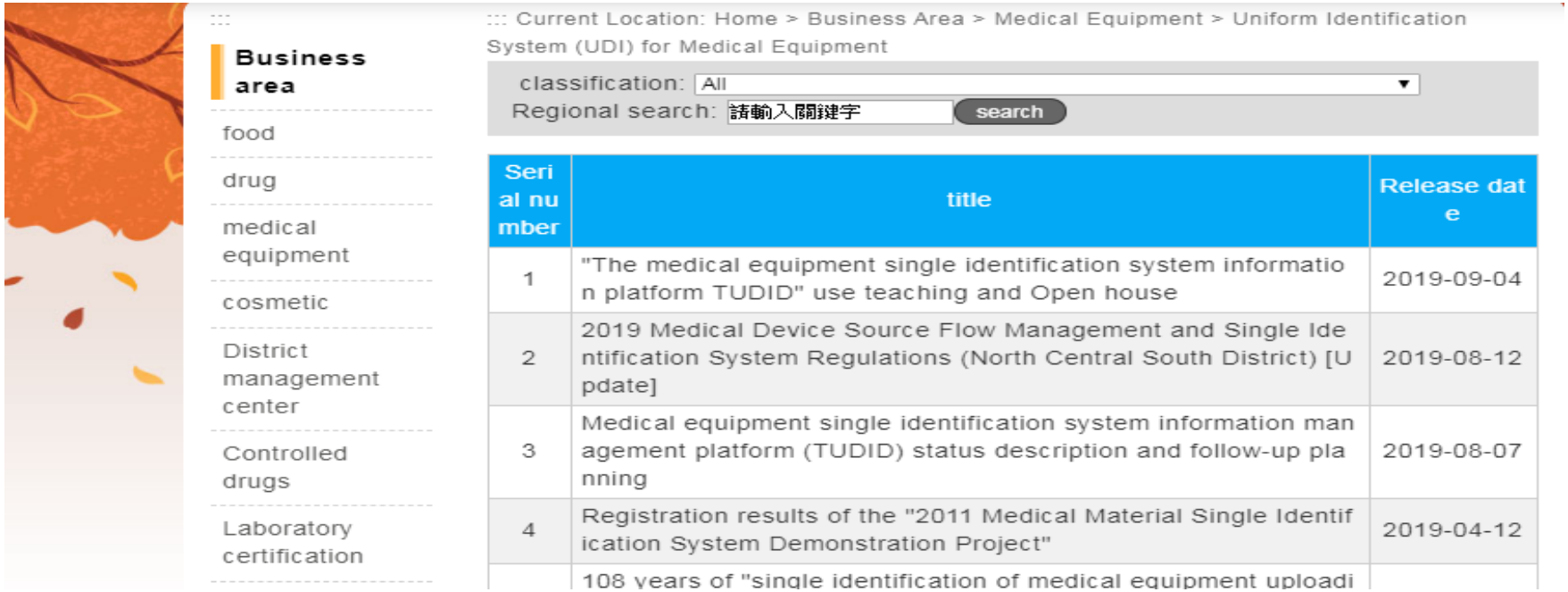
TFDA UDI Resources



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Business area

- food
- drug
- medical equipment
- cosmetic
- District management center
- Controlled drugs
- Laboratory certification

::: Current Location: Home > Business Area > Medical Equipment > Uniform Identification System (UDI) for Medical Equipment

classification: All

Regional search: 請輸入關鍵字 search

Serial number	title	Release date
1	"The medical equipment single identification system information platform TUDID" use teaching and Open house	2019-09-04
2	2019 Medical Device Source Flow Management and Single Identification System Regulations (North Central South District) [Update]	2019-08-12
3	Medical equipment single identification system information management platform (TUDID) status description and follow-up planning	2019-08-07
4	Registration results of the "2011 Medical Material Single Identification System Demonstration Project"	2019-04-12
	108 years of "single identification of medical equipment uploadi	

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Application by Hospitals

Application by Hospitals

The Adoption of GS1 UDI Standards - A Chief Cardiovascular Surgery Perspective

GS1 Healthcare Webinar

Dr. Chun-Che Shih, Chief of Division of Cardiovascular Surgery, Taipei Veterans General Hospital, Professor of Institute of Clinical Medicine National Yang-Ming University

Taiwan

Experience of clinical UDI applications with smart medical management system relying on GS1 standards

GS1 Healthcare Webinar

Dr. Shih-Chung Huang, Attending Physician of Cardiology; Director of Medical Education and Research Centre, Kaohsiung Armed Forces General Hospital (KAFGH), Chinese Taipei

May 22, 2019

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Experiences of Hospitals Implementing UDI

UDI brings benefits:

- Efficiency for hospital management to shorten recording time
- Accuracy for healthcare practices
- Easy and simplified accounting
- Income profits for hospital execution
- Energy saving and carbon reduction

UDI brings challenges:

- No UDI label or wrong UDI label
- DI code may change

Takeaway Points

- UDI is a key foundational building block. Longer transition periods ought to be given.
- It can be anticipated that UDI may be applied to the tracking and tracing of medical devices.
- For better patient safety, cooperation among dealers, competent authorities and medical institutions is necessary to interlink the whole tracking chain for medical devices.

Thank you for your attention!

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