National Health Surveillance Agency

Panel Discussion

UDI System Implementation

Medical Devices Webinar – Unique Devices Identification (UDI)
Thursday, January 27th, 2022
9:10 – 11:55 CT

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Brazil

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Agência Nacional de Vigilância Sanitária

UDI System Implementation in Brazil

Summary

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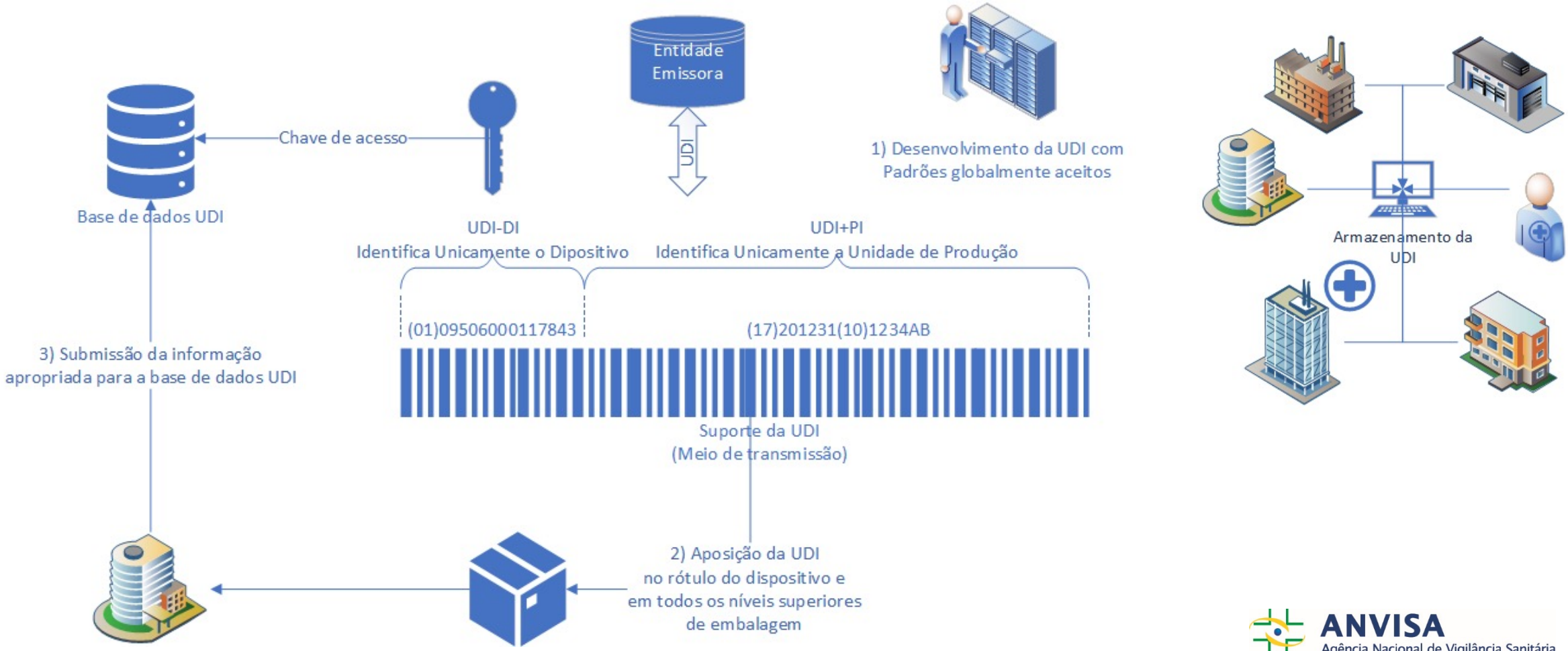
(20 minutes)

Unique Devices Identification

UDI System Framework



Development of the Regulation for Unique Devices Identification in Brazil

Alignment with Anvisa's Strategic Planning and Regulatory Schedule

Anvisa's Strategic Plan 20/23, Objective 3
Listed as Strategic Project

AGENDA REGULATÓRIA

2021-2023

Regulatory Schedule 21/23
Item 11.10 - Unique Devices Identification (UDI)
Process Number: 25351.910027/2021-96

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Development of the Regulation for Unique Devices Identification in Brazil

Timeline – Part I of III

IMDRF UDI Guidance (December 9, 2013)

July 7, 2020

UDI announced as a priority for Anvisa

IMDRF UDI System Application Guide (December 12, 2018)

Working Group at Anvisa on the Standardization of the UDI in Brazil

October 13, 2020 – April 18, 2021

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Development of the Regulation for Unique Device Identification in Brazil

Timeline – Part II of III

April 2021 – June 2021

Exempt from Regulatory Impact Analysis
Decree number 10.411/2020, Art. 4, Item VI
Normative aiming to maintain convergence to international standard

July 7, 2021 – September 6, 2021

Public Consultation Period

September 2021 – December 2021

Evaluation of the Public Consultation

December 2021

Deliberation of the Collegiate Board of Anvisa on the standardization of the UDI

January 04, 2022

Collegiate Board Resolution (in Portuguese, RDC) 591/2021 on UDI System

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Development of the Regulation for Unique Device Identification in Brazil

Timeline – Part III of III

January 2022 – Now

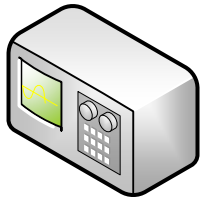
Start Planning the Information System Development Model

- Budget Savings
- Anvisa's Information Technology Planning

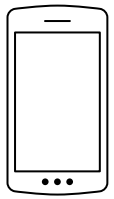
Scope of Unique Device Identification in Brazil

Medical Device Information in the Brazilian UDI Database – Part I of II

- Scope: all medical devices marketed in Brazil, including products for *in vitro* diagnosis.
  Exception: custom-made medical devices and medical devices under clinical investigation.

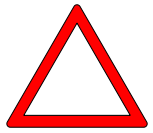


- Device Identification
  - Mandatory: UDI-DI (2), Commercial Name (7), Version or Model (8), # of Devices (1)
  - Conditional: UoU UDI-DI (4)
  - Optional: Catalog Number (9), Supplementary Device Description (11)



- Contact:
  - Mandatory: Manufacturer's information – name, address and customer service (5)
  - Optional: URL for Use Instructions (19)

- Packaging:
  - Mandatory: UDI-DI (2), Device Discontinuation Date (21)



- *Device Naming:*
  - Mandatory GMDN (6)

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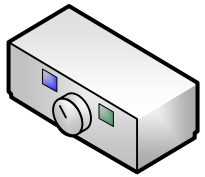
Scope of Unique Device Identification in Brazil

Medical Device Information in the Brazilian UDI Database – Part II of II



- Medical Device Features
  - Mandatory:
    - How the device production is controlled (3)
    - Is it labeled as a single-use device? (13)
      - If not, inform the maximum amount of times the device may be reused (14)
    - Is it labeled as sterile device? (15)
    - Is sterilization necessary before use? (16)
      - If so, what is the sterilization method? (17)
  - Conditional
    - Clinically Relevant Dimensional Features (10)
    - Storage or Handling Conditions (12)
    - Critical warnings or contraindications (20)
    - Presence of certain substances? (18)

Implementation Schedule for the Unique Device Identification in Brazil

UDI Implementation Schedule in Brazil
Affixing the UDI to the product, label and additional packaging

D_0 = January 4, 2021

Publication of RDC 591/2021

D_0 + 3 years

Medical devices of risk class III

D_0 + 6 years

Medical devices of risk class I

The term for each risk class can be extended in +2 years if the device is reusable and the UDI is placed on the device itself

Medical devices of risk class IV

D_0 + 2.5 years

Medical devices of risk class II

D_0 + 4 years

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Implementation Schedule for the Unique Device Identification in Brazil

UDI Implementation Schedule in Brazil
Submission of UDI data to Anvisa Information Systems

D_0 (to be defined)

Information System Made Available

D_0 + 3 years

Medical devices of risk class III

D_0 + 6 years

Medical devices of risk class I

The term for each risk class can be extended in +2 years if the device is reusable and the UDI is placed on the device itself

Medical devices of risk class IV

D_0 + 2.5 years

Medical devices of risk class II

D_0 + 4 years

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Discussion

Lessons Learned in the Process and Discussion on the Brazilian UDI Database Implementation

The support by the main stakeholders and senior managers has been key for the development of the UDI in Brazil

The creation of a working group with the main stakeholders reinforced Brazil's compliance with the IMDRF Guidelines

The pandemic has not affected the initial regulatory planning for the UDI System in Brazil

The current planning step for the development of the Brazilian UDI database has not yet been concluded.

There isn’t an out-of-the-box solution and everything indicates that it will be necessary to develop a customized software in Brazil

- Brazil struggles with the devaluation of the local currency (BRL) and the
- Qualified workforce seeks remote work abroad

Thank you

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General Management of Health Products Technology

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