



Experience in marking and traceability of medical devices: The case of Ecuador

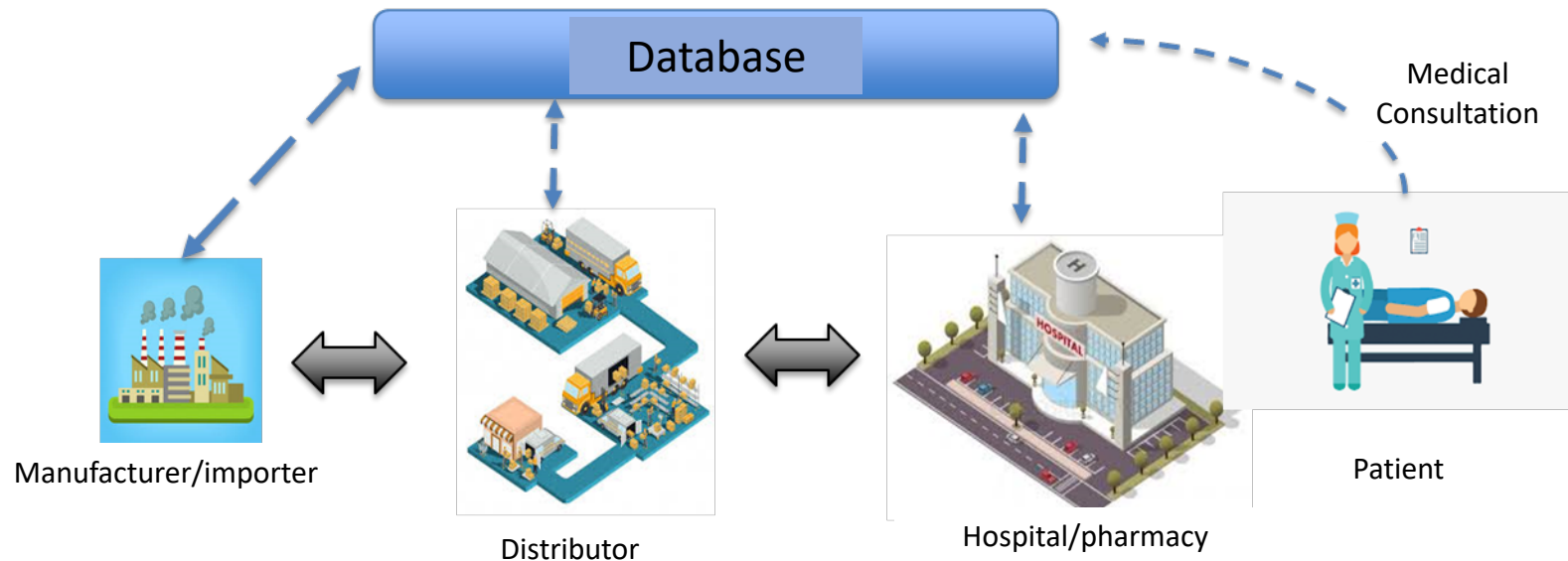
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National Agency for Regulation, Control and
Health Surveillance



Legal requirements

- Executive Decree 1033 year 2020 (individual and unambiguous identification)
- Resolution ARCSA-DE-030-2020-MAFG (Withdrawn by Decree 303)



Single traceability code marking

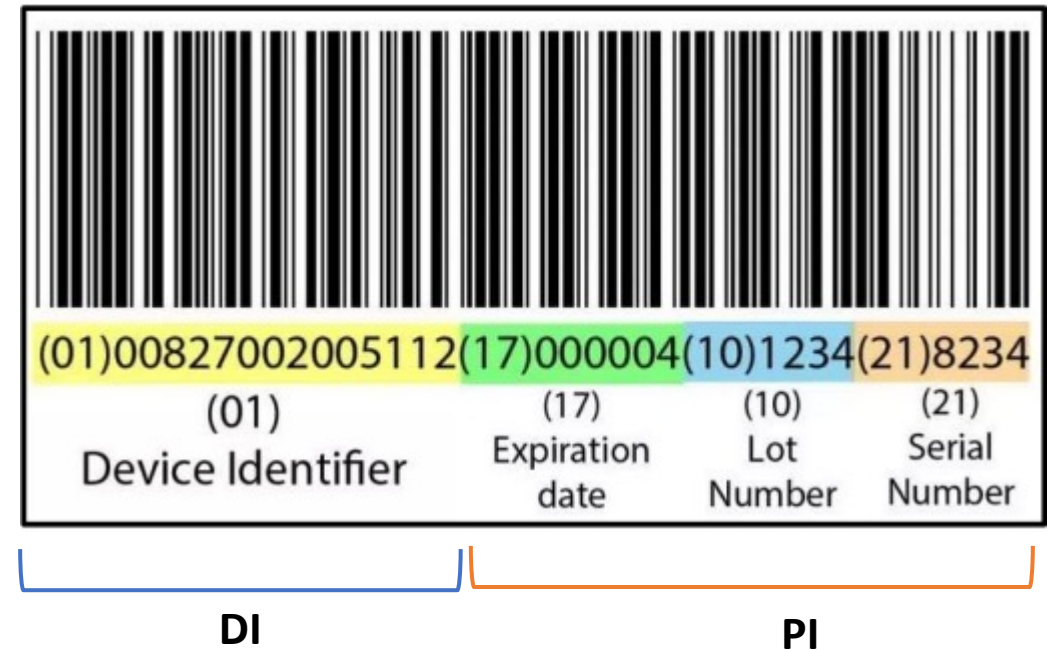
- IMDRF/UDI WG/N7 FINAL:2013
- IMDRF/UDI WG/N48 FINAL: 2019
- Guides and documents GS1



GTIN + Application ID



$$\text{UDI} = \text{DI} + \text{PI}$$



UDI Expected Benefits

Health Authority

- Visibility
- Market surveillance
- Harmonization to international standards
- Smuggling
- Reduction of losses and deterioration

Regulated

- Better sourcing planning
- Reaction to quality problems
- Supply chain efficiency
- Inventory management

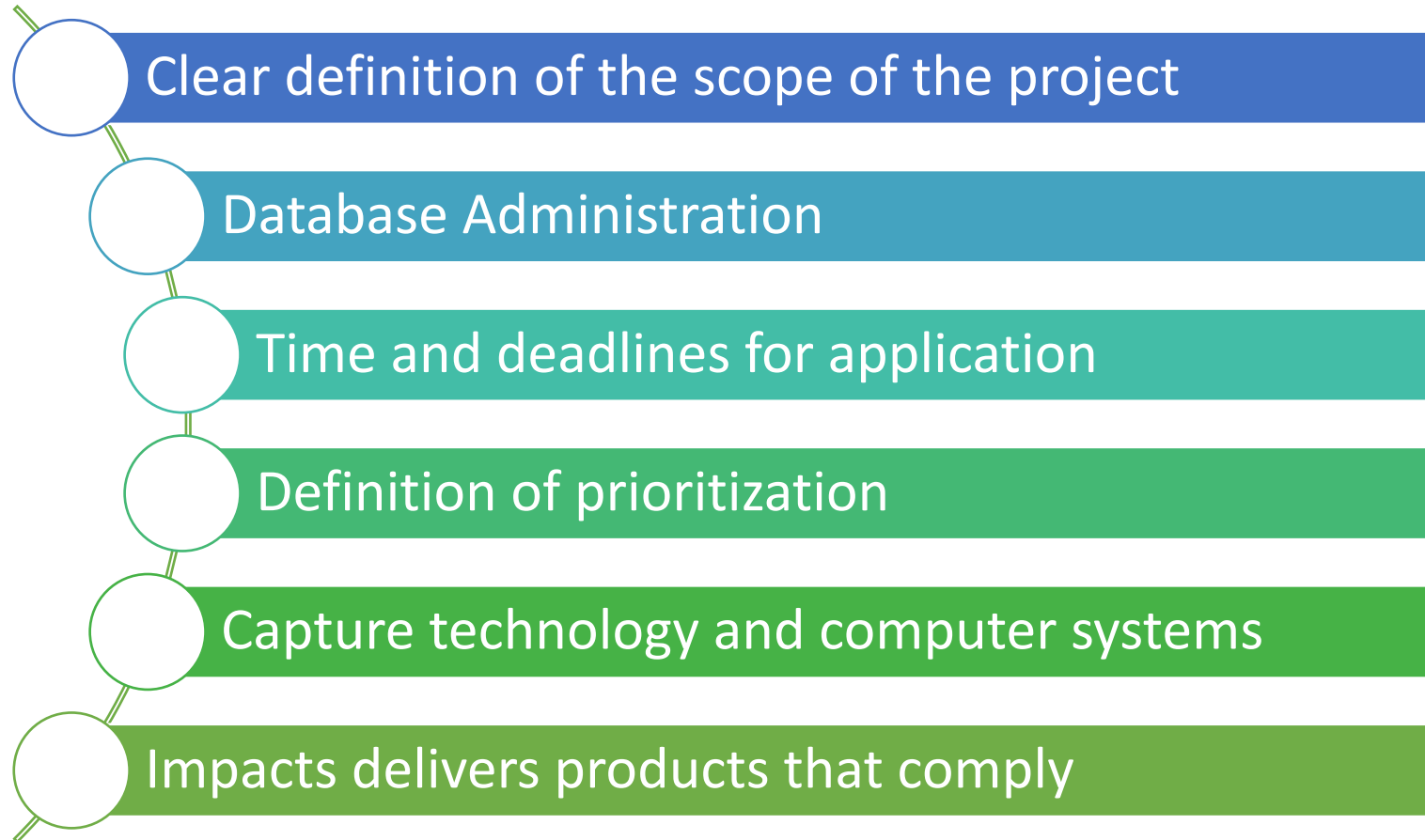
Hospitals

- Accurate identification
- Timely product information
- Procurement planning
- Improves adverse reports

Patients

- Dispensing control
- Safety and security
- Better treatment based on information and data analysis

Critical knots regulatory application



Pilot Implementation

- At the initiative of GS1 and the private sector, 17 participating companies
- 129 devices evaluated: 102 non-implantable and 27 implantable
- Objective: To determine the maturity for implementation in the country
- Scope: from import to delivery to the health network
- Conclusion:
 - GS1 recommends ARCSA align with IMDRF recommendations.
 - Variability in marking compliance related to GS1 checkpoints
 - 88.24% meet information requirements recommended by IMDRF
 - 0% meets identification requirement at the level of logistics units
 - 73% comply with the application of the traceability code, 45.4% (Data Matrix), 27.7 GS1 128
 - 58.8% mandatory traceability control points

New Presidential Decree December 28, 2021

That it is necessary to streamline and improve the system of acquisition of health services and services, guaranteeing the quality of products, the correct use of public resources and, especially, avoiding the shortage of the Integral Public Health Network, RPIS; and

In the exercise of the power conferred by article 147 of the Constitution of the Republic of Ecuador, in accordance with article 129 of the Organic Administrative Code;

DECREES:

Sole article.- Executive Decree No. 1033 published in the Supplement to the Official Register No. 208 of May 21, 2020, shall be withdrawn; and any rule of equal or lower hierarchy that contravenes the provisions of this Executive Decree shall be withdrawn.

FINAL PROVISION:

ONLY.- This Executive Decree shall enter into force upon its publication in the Official Register.

Given in the city of Santiago de Guayaquil, on December 28, 2021.



Guillermo Lasso Mendoza
PRESIDENTE CONSTITUCIONAL DE LA REPÚBLICA

National Agency for Regulation, Control and
Health Surveillance



LESSONS LEARNED



AGENCIA NACIONAL DE REGULACIÓN, CONTROL Y VIGILANCIA SANITARIA

Para que tú estés bien, hacemos las cosas bien.

THANK YOU

National Agency for Regulation, Control and
Health Surveillance



República
del Ecuador



Juntos
lo logramos