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Semantic standard and coding of medical devices for human use IMD

Directorate of Medicines and Health Technologies

Content

01.

Regulatory context

1. REGULATORY CONTEXT

Article 25 of Decree Law 4107 of 2011 states that the Ministry of Health and Social Protection, through the Directorate of Medicines and Health Technologies, must develop guidelines for the identification and classification of medical devices that facilitate sanitary and epidemiological surveillance.

Article 117 of Decree Law 019 of 2012, amending Article 91 of Law 1438 of 2011, states that the Ministry of Health and Social Protection will issue the norm that allows the codification of medical supplies and devices, whose use and destination will be the General System of Social Security in Health (SGSSS).

1. REGULATORY CONTEXT

Resolution 2535 of 2013 regulating Decree Law 019 of 2012, defines the semantic standard and determines its objectives for the SGSSS

1. MD identification and classification.
2. Handling, supply, acquisition and use.
3. Expenditure management.
4. Exchange of information
5. Traceability
6. Price regulation

} Require other special regulations where the semantic standard and MD coding is used

02.

Current problems

2. CURRENT PROBLEMS

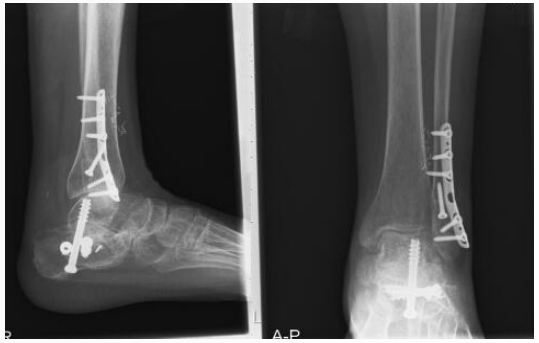
1) Inconsistent information, leading to unjustified recoveries by:

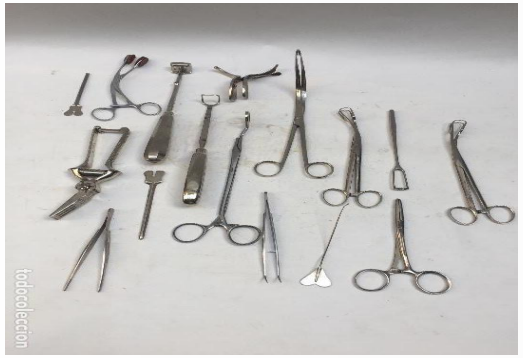
- Include MD with multiple denominations with different prices.
- Include instruments such as implantable MD.
- Include items such as equipment rental and others.
- Include osteosynthesis material by commercial presentation and not by unit of use. E.g. Screw per set of 20, glucose strips per bottle of 50.

2. CURRENT PROBLEMS

2) Groups of MD of different risks for collection as the highest.

III Risk





IIB Risk

03.

Definition of semantic standard and coding of medical devices

3. Semantic Standard Definition and Medical Device Coding

It is a computer technology instrument used to organize standardized medical device information, which is translated into an Identifier Code (IMD) of the products, which data is interoperable within the SGSSS.

Semantic standard Common language for **uniformly naming** a medical device.

Titanium threaded screw FR219456

Coding A combination of letters and/or numbers that **identify** a **product.**

3.1 STANDARD ALTERNATIVES

COMPARATIVE TABLE INTERNATIONAL STANDARDS

AGENCY	MD TYPOLOGIES	USES	CHARACTERISTICS	COSTS
Global Medical Device Nomenclature GMDN (United Kingdom)	Total Universe of Generic MDs	those required by the country	Integrates 6 models. USA, some countries in Europe and Asia ISO 9999. ISO 15125 methodology. A 5-digit smart code with information from the generic name of the MD, technical information and usage. Multiaxial database, interoperable data.	Free for regulators. Free companies up to 200 codes Annual Memberships GMDN

3.1 STANDARD ALTERNATIVES

COMPARATIVE TABLE INTERNATIONAL STANDARDS

AGENCY	MD TYPOLOGIES	USES	CHARACTERISTICS	COSTS
Universal Medical Equipment Nomenclature System UMNDS (ECRI) USA	Biomedical Equipment, some types of MD	Inventories in hospitals	A 5-digit numeric code. Generic name of the medical device, with technical information. Non-interoperable database. MD Unique Code	Free
MD-UDI Unique Code (FDA)	Medical Devices of the American and European markets		Standardizes manufacturer and MD FDA and EUDAMED data Manufacturer code	Free

3.2 STRUCTURE (CHARACTERISTICS) OF THE SEMANTIC STANDARD AND CODING OF MEDICAL DEVICES.

- GMDN Code Equivalent: 6 digits
- Manufacturer Code: 7 digits
- Product reference code: 6 digits

Basic Attributes - Key

Drag the following information

- Unique Code of Procedure in Health CUPS
- UDI-DI Code

Clinical attributes

3.2 STRUCTURE (CHARACTERISTICS) OF THE SEMANTIC STANDARD AND CODING OF MEDICAL DEVICES.

- Owner, manufacturer, importer, file, risk, modality, unit of use, storage condition and packaging

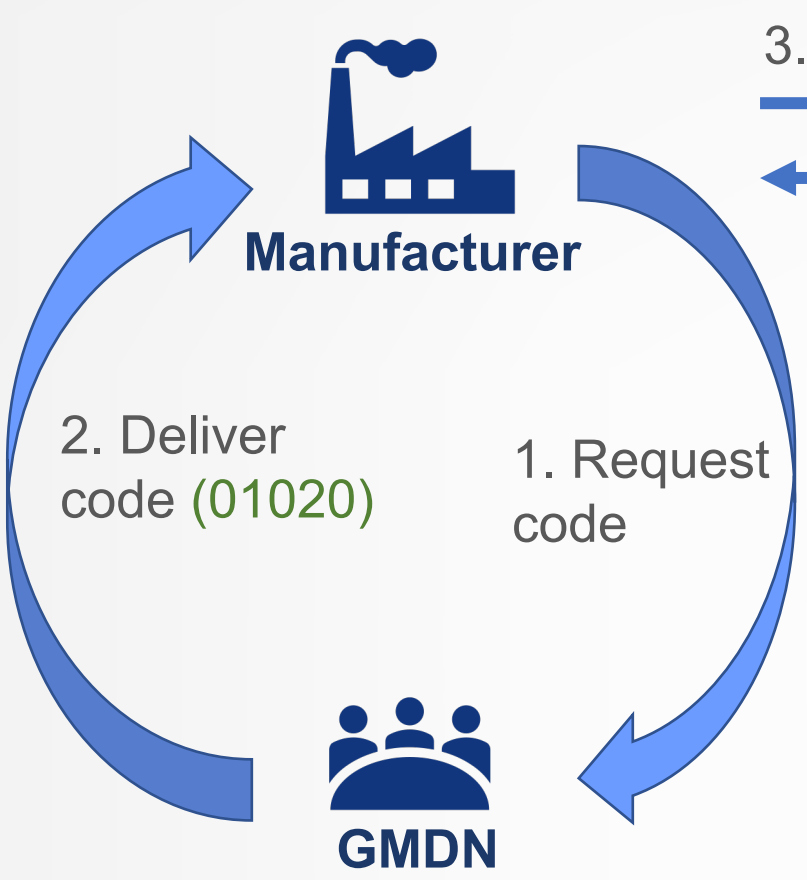
Regulatory attributes

- Commercial description (brand, trade name)

Business attributes

Note: The GMDN itself does not include data of the local regulations, it only contains information of the denomination and characteristics of the MD (standardized).

3.2 IMD GENERATION PROCESS



3. Request IMD and Sanitary Registration (01020)

4. INVIMA **generates IMD**:

Code equivalent to GMDN

Tx(01020) = **123456**

+

Manufacturer's Code

+

Product Reference Code

Generated by Algorithms

5. Send standard **data**

3.3 WHAT DOES IMPLEMENTATION INVOLVE?

Manufacturers

- Payment annual membership to the GMDN Agency, depends on the available burget of the company.
- Purchase of code for each MD if it exceeds 200 codes
- Provide the GMDN code and commercial presentations (set, unit, kit) to the holder or importer of the SR in Colombia.

Holders or importers

- Report the same RS information + the GMDN code + CUPS + Unit of use in the INVIMA application.
- Adjustments to business information systems for your business transactions.
- Payment for sanitary registrations of anomalous groups.

EPS – IPS

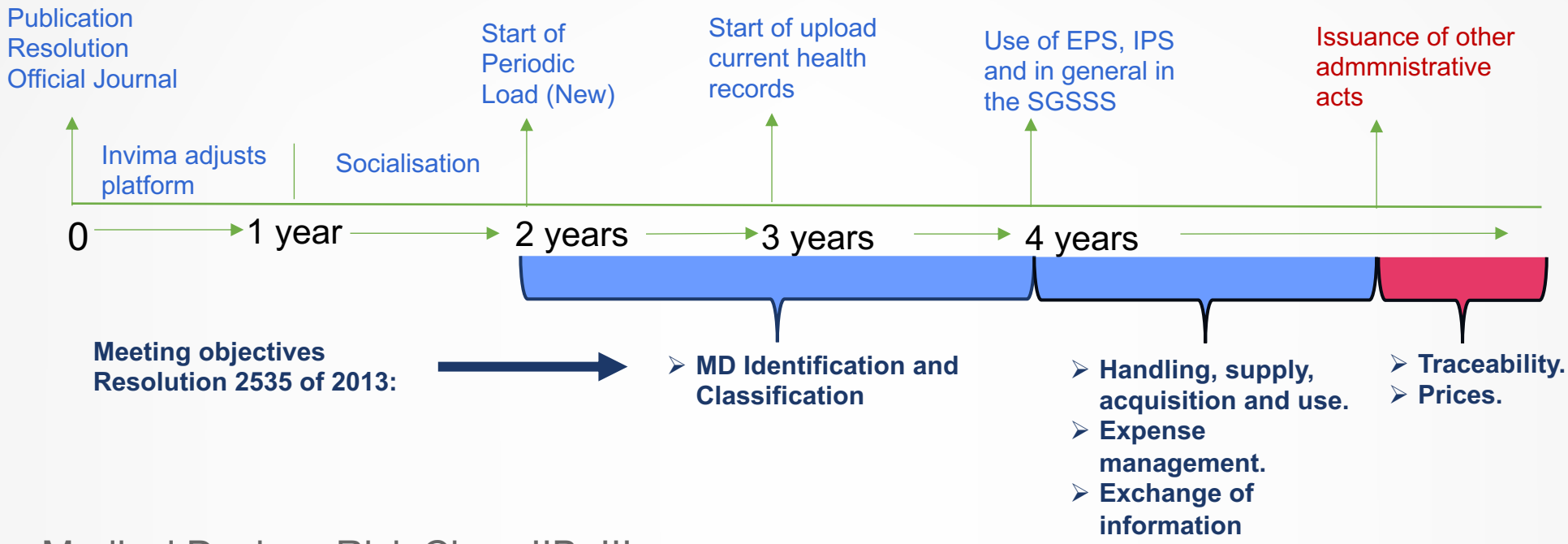
- Adjustments in institutional information systems (procurement, inventories, invoices and collections, RIPS records.

3.3 WHAT DOES IMPLEMENTATION INVOLVE?

<table>
<tr><th>PHASES</th><th>STAKEHOLDERS</th><th>Products</th><th>Risk</th><th colspan="2">Total Health Risks
Cut January 31 2019- Invima</th></tr>
<tr><td rowspan="4">PHASE I
Stages I and II
Upload information</td><td rowspan="4">RS holders, Importers and manufacturers.</td><td rowspan="2">Medical Devices (Includes biomedical equipment)</td><td rowspan="2">IIB and III</td><td colspan="2">4.928</td></tr>
<tr><td>Domestic manufacturers
368</td><td>Foreign manufacturers
2.371</td></tr>
<tr><td rowspan="2">In vitro diagnostic reagents</td><td rowspan="2">II and III</td><td colspan="2">3.579</td></tr>
<tr><td>Domestic manufacturers
17</td><td>Foreign manufacturers
296</td></tr>
<tr><td>PHASE II</td><td colspan="5">Use of the IMD for the SGSSS (insurers, providers, industry): purchasing, procurement, inventory, processes, etc.
Use Ministry, ADRES, Health Authorities: Price regulation, Collections, surveillance and control, traceability, etc.</td></tr>
<tr><td>PHASE III</td><td colspan="5">List of medical devices risk class IIA and I to standardize and code according to criteria, e.g. Recoveries, adverse events, falsification and others.</td></tr>
</table>

3.3 WHAT DOES IMPLEMENTATION INVOLVE?

IMPLEMENTATION TIME AND OBJECTIVES TO BE MET



Medical Devices Risk Class IIB, III
In vitro diagnostic reagents Risk Class II, III

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THANK YOU!

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