REGULATION SYSTEM OF MEDICAL DEVICES IN LEBANON

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PLAN

• Medical devices policy at the Ministry of Public Health
• Regulatory framework for MD
• The way forward...
Context analysis

• Similarity with neighboring markets.
• Low local production capacity => Total dependence on the import from multinational firms.
• Weak regulatory environment leaves seep products not always complying with the minimum security requirements
• Dominance of private providers with excessive and profitable high technology services implemented and offered with almost no controls or evaluation.
• Excess supply of physicians and an imbalance between specialists and general practitioners
• No systematic evaluation of safety and benefits.
• Incapacity to perform testing and premarket evaluation for medical devices
National policy for MD

Promotion of continuous improvement of quality of care and patient safety. MoPH adopted a national strategy with an approach that emphasizes:

• Cohesive policies between phases of the medical device life cycle: a harmonized health technology regulation, an appropriate health technology assessment and a global health technology management.

• Transparency, consistency and large participation of all stakeholders.

• Regulatory framework focusing on quality and security through products’ compliance with international standards to reduce the risks associated with the use of non-compliant products.

• Post-marketing surveillance in accordance with recent international guidelines, the establishment of a traceability and vigilance system for implantable high-risk products (class IIb and III).
MoPH – Ansm Cooperation project

• Exploratory mission carried out in April 2010
• Protocol signed in January 2011
• Cooperation is taking place in the following areas:
  - **Exchange of information** on drugs, mostly generic (quality, efficiency and safety) and medical devices
  - Scientific and practical cooperation in the field of quality, effectiveness and safety of drugs and medical devices
  - **Skills’ development** (training of MOH staff).

Ecole Supérieure des Affaires in Beirut (ESA) is the implementation operator for this cooperation.
Objective

1. To ensure that the imported MDs meet the minimum requirements of quality and safety
2. To be able to retrieve products subject to recalls in case of incident.

Action plan to establish a medical devices (MD) regulatory system:

- Requirements for importation of MD
  (Establishment of a national procedure for importation of MD)
- Registration of implantable MD/implantable MD suppliers
- Follow up on implantable MD importation
- Traceability of MD.

Priority is given to the optimal use of resources for market knowledge and the exercise of a minimum post-marketing surveillance which will follow up any health measures following the recent international orientations.
International experience in regulation of medical devices

• The Global Harmonization Task Force (GHTF) was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry: representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework.

• Purpose: to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade.

• Publication and dissemination of harmonized guidance documents on basic regulatory practices adopted/implemented by member national regulatory authorities.

• Served as an information exchange forum through which countries with medical device regulatory systems under development could benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

• IMDRF was born in October 2011, to build on the strong foundational work of the GHTF on Medical Devices and to accelerate international medical device regulatory harmonization and convergence.

• Current members are Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, and the USA.

• The World Health Organization (WHO) and the APEC LSIF Regulatory Harmonization Steering Committee are Official Observers. The Asian Harmonization Working Party (AHWP) and the Pan American Health Organization (PAHO) are IMDRF Affiliate Organizations.
The Global Medical Device Nomenclature (GMDN): list of generic names used to identify all medical devices (used in diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans).

**Purpose:** to provide a naming system that can be used to exchange medical device information and support patient safety.

GMDN is used for:
- Data exchange between manufacturers, regulators and healthcare authorities
- Exchange of post-market vigilance information
- Supporting inventory control in hospitals
- Purchasing and supply chain management

Recommended by the International Medical Device Regulators Forum (IMDRF) and used by over 70 national medical device regulators.

Managed by the GMDN Agency which has a Board of Trustees, which represent regulators and industry.

GMDN Database: Information in the form of a 5 digit numeric GMDN Code is cross-referenced to a precisely defined Term Name and Definition.

**Example:**
- **GMDN Term Name:** Scalpel, single-use
- **GMDN Code:** 47569
- **GMDN Definition:** A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.
1. **Decisions Overview**

<table>
<thead>
<tr>
<th>Decisions no.</th>
<th>• 455/1 &amp; 1506/1</th>
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</thead>
</table>
| Issuance Date: | • 16 April 2013  
• 1 September 2014 |
| Effective Date: | • July 1\(^{st}\), 2013  
• April 1\(^{st}\), 2015 |
| Objective: | • To guarantee the safety and quality of all medical equipment, supplies and instruments that are sold in the Lebanese market and used in various medical procedures. |
| Content | • 10 articles detailing the entire process  
• 7 items detailing implementation of 455/1 |
2. Field of application

- "Medical devices that are not covered by the Drug Registration Technical Committee (law 367/94) nor by decree 5518" should be listed/registered.
- Medical devices classified into 16 categories according to GMDN agency classification:
  1. Active implantable devices
  2. Anesthetic and respiratory devices
  3. Dental devices
  4. Electro mechanical medical devices
  5. Hospital hardware
  6. In vitro diagnostic devices
  7. Non-active implantable devices
  8. Ophthalmic and optical devices
  9. Reusable devices
  10. Single-use devices
  11. Assistive products for persons with disability
  12. Diagnostic and therapeutic radiation devices
  13. Complementary therapy devices
  14. Biologically-derived devices
  15. Healthcare facility products and adaptations
  16. Laboratory equipment
3. General Process

- **Imported products**
  - **Application of related regulations** (drugs or food supplements and natural products)
    - Yes
    - **Covered by law 367/94 Or decree 5518??**
      - No
      - **Is it an implantable device?**
        - Yes
        - **Medical devices listing in MDRS within the Projects & Health Systems unit (MoPH)**
        - **Implanted medical devices registration process within the Projects & Health Systems unit (MoPH)**
      - **No**
Registration Process as defined in the national procedure
4. Traceability Records & vigilance system

**Article 8: Traceability Records**

**Suppliers’ Required Records**

- Traceability record (Import Date; Quantity; Entities that received the goods)

**Healthcares’ Facility Required Records**

- Keep records of all patients who received the implanted medical devices, including patient name, address and telephone number.

**Article 9**: "Notify the MOH of all unexpected adverse events and side effects resulting from the use of these products".
5. Decision 1506/1

1. Definition of a MD
2. Adoption of GMDN nomenclature system
3. Classification of MD
4. Additional compliance certificates
5. Amendment of DMI identification form
6. Deadline
Medical devices registration software (MEDReg)

- Company’s Administrative Profile
- Device Specification (Components, Functions, Scope of use...)
- Sterilization Method
- Certificate of Conformity
Medical devices registration software (MEDReg)

<table>
<thead>
<tr>
<th>IMS/Category</th>
<th>Event/Date</th>
<th>Event/Date</th>
<th>Event/Date</th>
<th>EC-Pack quality assurance</th>
<th>CE Marking of Conformity</th>
<th>Fre Sale Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>27/09/2021</td>
<td>23/06/2014</td>
<td>27/09/2018</td>
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<td></td>
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<tr>
<td>27/09/2014</td>
<td>23/06/2014</td>
<td></td>
<td>12/12/2015</td>
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### Technical Description
- **Implantable materials:**
  - Implantable materials are made from high-grade medical-grade silicone rubber.
  - The incision is made in a sterile environment.
  - The materials are validated and confirmed to ISO 11607 standard.

#### Scope of Use / Function
- **For Treatment:**
  - **Specialties:**
    - Orthopedics
    - Plastic Surgery
    - Urology
    - Gastroenterology
    - Neurology
    - Ophthalmology
    - Obstetrics
    - Gynecology
    - Cardiovascular
    - Dentistry
    - Respiratory
    - Urology
  - **Devices:**
    - Implantable devices
    - Sterilization Module
  - **Implantable Devices:**
    - Implantable devices are regularly updated and validated.
  - **Sterilization Module:**
    - Electron beam sterilization is commonly used.
  - **Dental:**
    - Dental implants are continuously evaluated and validated.
  - **Urology:**
    - Urology devices are regularly updated and validated.

### Summary
- **General Manager:** Jean-Pierre Aoun.
MoPH – Follow up on Importation of MD

- **Goal**: to ensure that only implantable MD compliant with minimum quality and safety requirements are imported to the Lebanese market

- Implemented within the departments in charge of invoice endorsement (pharmacy for sterile items and health engineering departments for non sterile)

- Invoices uploaded by suppliers

- Linked to MEDReg

- Training sessions are provided to the suppliers in order to ensure satisfactory implementation.
MoPH – Follow up on Importation of MD
MoPH – Traceability of MD Module (MEDTrac)

- **Goal**: to track the use of the medical devices by hospitals.
- Allow all hospitals to register the medical devices implanted for each case.
- Hospitals will access this module online.
- MEDTrac will be linked to MedReg and MedImport in order to validate registered data.
MoPH – Traceability of MD Module (MEDTrac)
Uploaded data

<table>
<thead>
<tr>
<th>Supplier data</th>
<th>Medical Device Data</th>
<th>Patient Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Supplier ID (from MedREG.)</td>
<td>1. Device Label Data (Reference number, Device Name, UDI, Lot Number, Expiry date, Serial Number)</td>
<td>National ID if available</td>
</tr>
<tr>
<td>2. Supplier Name</td>
<td>2. Manufacturer name (retrieved from MedReg or registered by the user if not found)</td>
<td>First name</td>
</tr>
<tr>
<td>3. Supplier Focal person name</td>
<td>3. Quantity</td>
<td>Middle name</td>
</tr>
<tr>
<td>4. Supplier Phone Number</td>
<td>4. Device registration code: if the supplier and the reference number are registered in MedReg, the system will retrieve the code of the device automatically.</td>
<td>Last name</td>
</tr>
</tbody>
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<thead>
<tr>
<th>Hospitalization data</th>
<th>Guarantor</th>
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<tbody>
<tr>
<td>Hospital ID</td>
<td>Name</td>
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<tr>
<td>Hospital name</td>
<td>Approval number (if not private)</td>
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<tr>
<td>Date of admission</td>
<td>Doctor’s Syndicate number</td>
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<tr>
<td>Diagnosis on discharge (ICD10 code)</td>
<td>Doctor’s Name.</td>
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Achievements

✓ **National procedure for the importation of medical devices** (November 2013)
  Defining the minimum safety and quality requirements for the importation of medical devices into the Lebanese market and objective criteria for the validation of submitted documents

✓ **Standard Operation Procedure for MD registration** (September 2014)

✓ **Standard Operation Procedure for importation of medical devices** (October 2015)

✓ **Procedure for traceability and declaration of adverse events** (April 2017)
  To identify patients holding a MD if a corrective action is needed and to identify the MD in case of incident.

✓ **Establishment of:**
  ✓ **MD Registration System (MEDReg)** – developed and implemented in application of decision 455/1 (for implantable MD)
  ✓ **MD Importation System (MED’Import)** – developed, tested, implementation in progress
  ✓ **MD Tracking System (MEDTrac)** – developed, testing in progress
The Way forward...

- Coordination with the customs and IRI
- Institutionalization of the established MD Regulatory System
- Pre-marketing phase: Dissemination and follow-up of procedures and rules for the evaluation and import of DMI and extension to other categories of MD.
- Post-marketing phase: Implementation of the IMD traceability and establishment of the materiovigilance system
### 1. Organisation administrative: institutionnaliser le système de réglementation des DM établi

<table>
<thead>
<tr>
<th>Numéro</th>
<th>Action</th>
<th>Acteurs</th>
<th>Intervention</th>
<th>Expert</th>
<th>Ansm</th>
<th>Date d’envoi du MSP</th>
<th>Durée de réponse de l’Ansm</th>
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<tbody>
<tr>
<td>1.1</td>
<td>Assurer le suivi avec les instances concernés sur la création de l’unité des technologies de la santé au MSP et recrutement des cadres</td>
<td>MSP</td>
<td>Assurer la formation du personnel (modalités à fixer ultérieurement)</td>
<td>2018-2019</td>
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<tr>
<td>1.2</td>
<td>Institutionnaliser le cadre réglementaire à travers les décrets et arrêtés nécessaires pour la création et la formation des comités d’évaluation des DM et la surveillance post commercialisation</td>
<td>MSP</td>
<td>2019</td>
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<td>1.3</td>
<td>Intégration des aspects réglementaires établis dans les procédures réglementaires du MSP (conformité, validation, contrats avec les hôpitaux)</td>
<td>MSP</td>
<td>2018-2019</td>
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### 2. Phase pré-commercialisation: Diffuser et sortir des procédures et des règles pour l’évaluation et l’importation des DM et étendre à d’autres catégories de DM

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<thead>
<tr>
<th>Numéro</th>
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<th>Ansm</th>
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<tr>
<td>2.0</td>
<td>Suivi et maintenance des systèmes MEDReg et MEDImport</td>
<td>MSP</td>
<td>2018-2019</td>
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<tr>
<td>2.1</td>
<td>Extension du système établi pour les dispositifs médicaux implantables (DMI) aux autres catégories des dispositifs médicaux: Établissement des priorités à adresser</td>
<td>MSP - Ansm</td>
<td>Lecture et commentaires des documents</td>
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<td>2.2</td>
<td>Fourniture du personnel des départements concernés au MSP</td>
<td>MSP - Expert</td>
<td>2018-2019</td>
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<tr>
<td>2.3</td>
<td>Définition des mécanismes de coordination avec les parties prenantes (douanes, IRI) pour la diffusion du système réglementaire établi</td>
<td>MSP</td>
<td>Modèles à éxécuter ultérieurement</td>
<td>2018-2019</td>
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<td>2.4</td>
<td>Identification en file des produits importés (filière par les importateurs)</td>
<td>MSP</td>
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<td>2.5</td>
<td>Organisation d’un séminaire pour la présentation du système de réglementation des DMI</td>
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<td>Participation au séminaire de publication</td>
<td>2019</td>
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<td>2.6</td>
<td>Modification des procédures opérationnelles pour le suivi des importations des DMI pour inclure les modalités pour les non importables et établissement d’un code de bon usage à signer par les fournisseurs</td>
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<td>2.7</td>
<td>Établissement des modalités de suivi des déclarations des événements indésirables et schéma national d’organisation, définition des responsabilités des acteurs</td>
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<td>2.8</td>
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<td>2.9</td>
<td>Organisation d’un séminaire pour la présentation du système réglementaire établi</td>
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### 3. Phase post-commercialisation: mise en place de la traçabilité des DMI et établissement du système de matériovigilance

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<thead>
<tr>
<th>Numéro</th>
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<th>Ansm</th>
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<tr>
<td>3.1</td>
<td>Mise en application du système de traçabilité des DMI sur le territoire Libanais</td>
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<td>3.2</td>
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<td>3.3</td>
<td>Établissement du cahier des charges pour l’établissement et le développement du système de matériovigilance</td>
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<tr>
<td>3.4</td>
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<td>3.5</td>
<td>Analyse et conception du module de suivi de la matériovigilance MEDVig</td>
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<td>3.7</td>
<td>Test, formation et déploiement de la matériovigilance</td>
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<td>2021</td>
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