REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

MoPH Cooperation Projects with French Ministry of Social Affairs and Health

REGULATING THE IMPORTATION & USE OF MEDICAL DEVICES

Ecole Supérieure des Affaires – December 18, 2013

Sizar AKOUM, IBMH

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Context of the project

- Globalization and rapid advances in health technologies (medicines, vaccines, medical devices) = countless benefits and improved quality of lives
- Increasing sophistication and development of cutting edge technologies => financial and technical challenges to national authority to ensure safety, quality, efficacy and effectiveness.
- International trends towards harmonization and reinforcement of regulation regarding medical devices.
- World Health Assembly adopted resolution WHA60.29 in May 2007:The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices.

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Context of the project

Health technology regulation (HTR), health technology assessment (HTA) and health technology management (HTM) = complementary functions to ensure the appropriate introduction and use of medical devices.

Source: WHO Medical device technical series, Health technologies assessment of medical devices

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Situation analysis

- Lebanon is a medical devices import country.
- Health sector dominated by private providers leading to high technologies implemented with no control or evaluation of its safety, efficacy or cost effectiveness => high impact on health bill.
- Excess supply of physicians and imbalance between specialists and general practitioners.
- Lack of regulations and follow-up resources.
- Incapacity to perform testing and pre-market evaluation for MD
- Inexistence of post-market surveillance to avoid unsafe products.

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

National policy for MD

MoPH adopted a national strategy with an approach that emphasizes:

- Establishing and implementation of a the 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)
- Supporting development of quality management systems covering the procurement process: The pre -qualification of suppliers, identifying the need, selection, purchase and use.
- Capacity building and promotion of appropriate use of medical devices: Development and dissemination of information, educational and communication programs.

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

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.

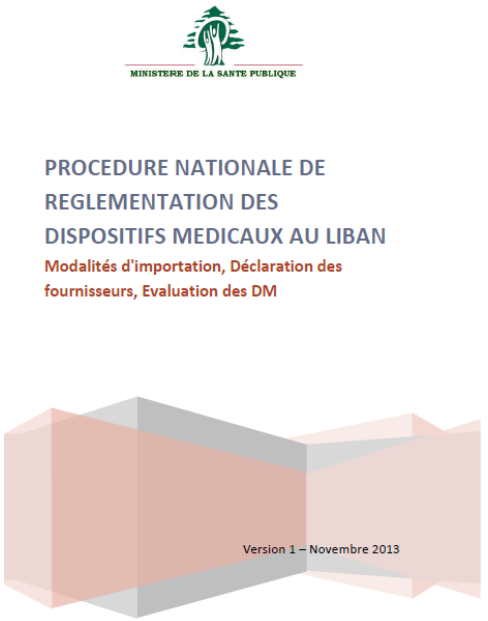
REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

MoPH – Ansm Cooperation project

Plan of action to:

Establish of a medical devices (MD) regulatory system:

- Requirements for importation of MD
- Registration of MD/ suppliers
- Traceability of MD.



→ Establishment of a national procedure

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

1. DECISION OVERVIEW

Decision no.	• 455/1
Issuance Date:	• 16 April 2013
Effective Date:	• July 1st, 2013
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

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

2. Field of application

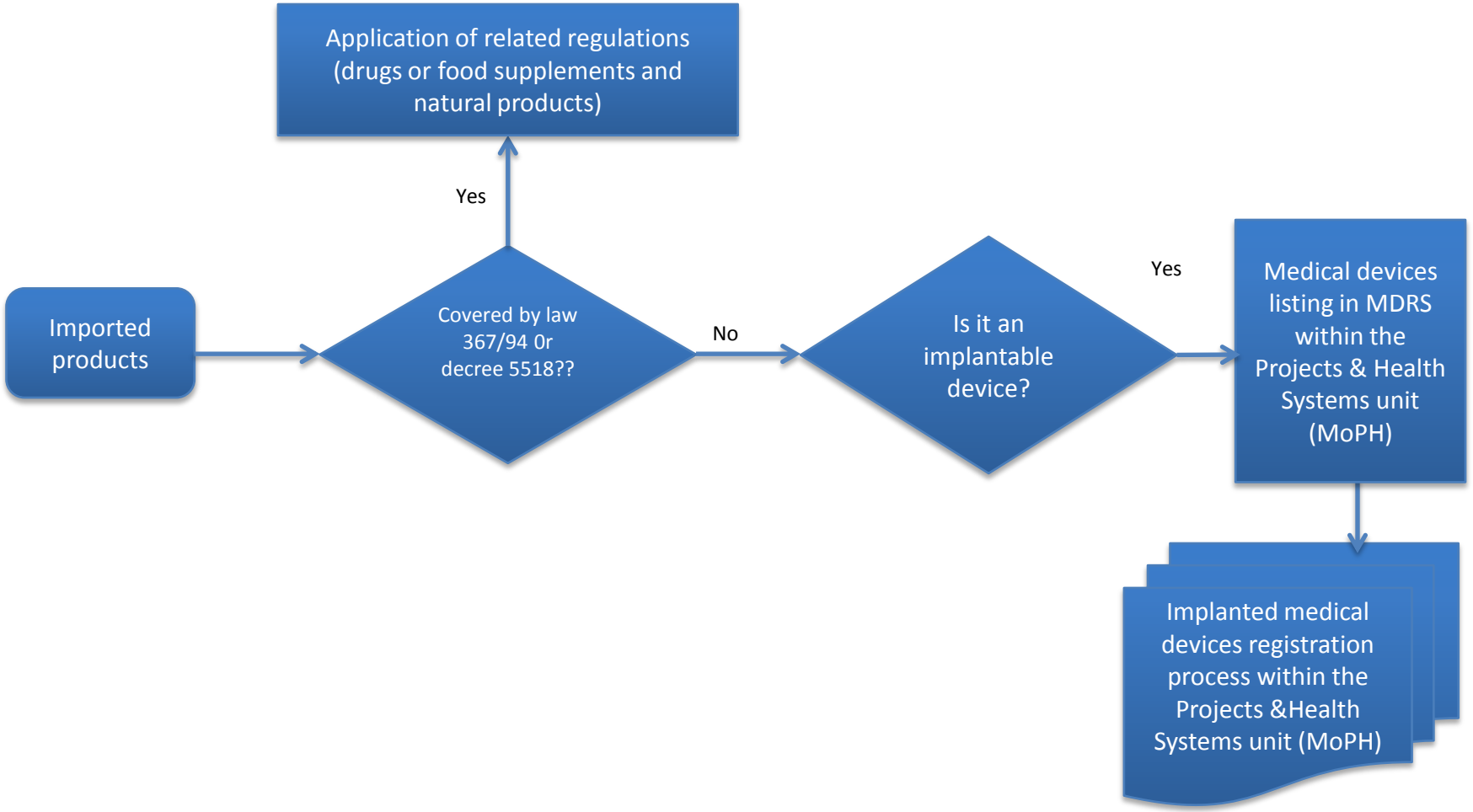
- "medical devices **that are not covered** by the Drug Registration Technical Committee (law 367/94) nor by decree 5518" should be listed/ registered.

- 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

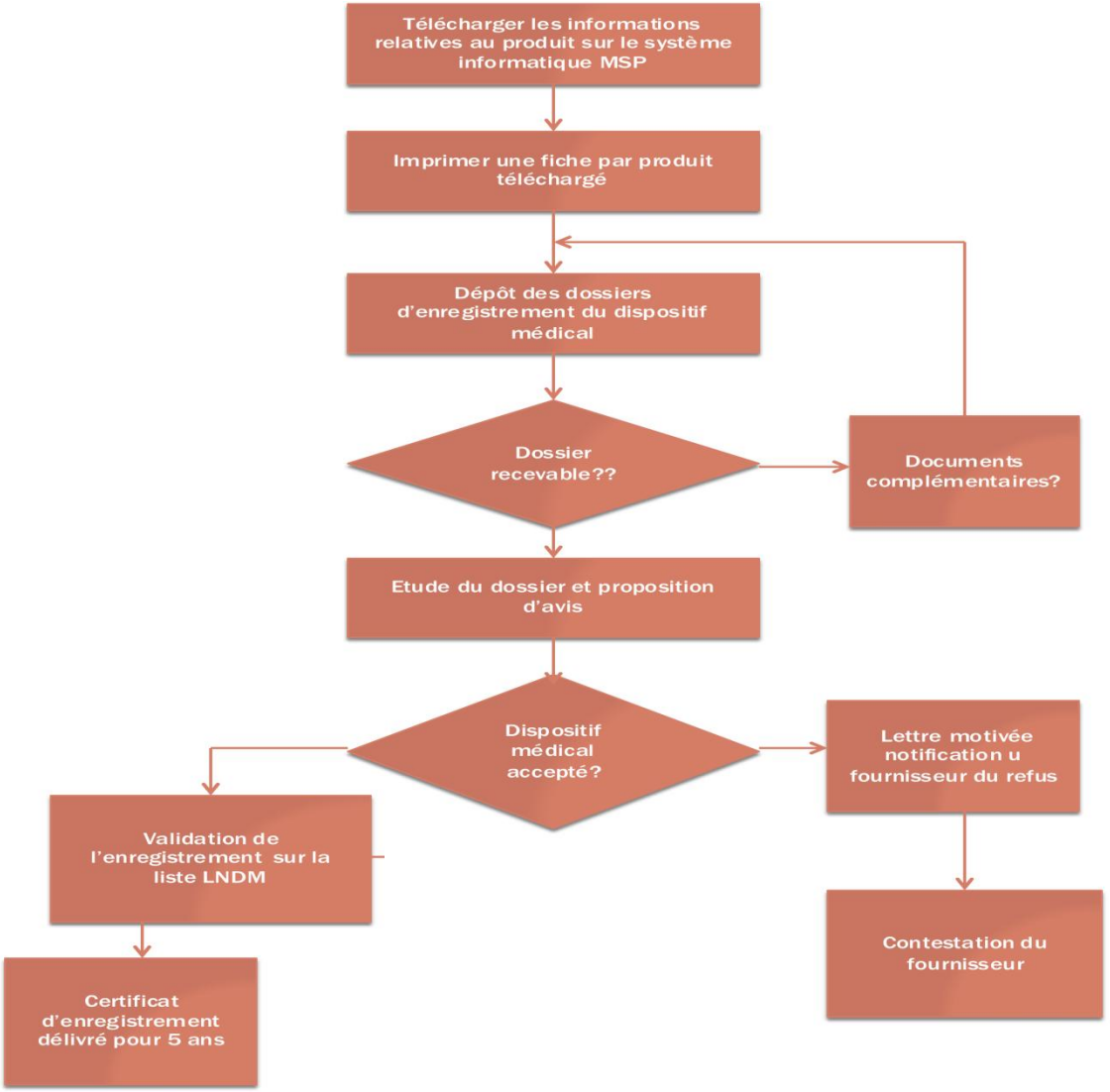
REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

3. General Process



REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Registration Process as defined in the national procedure



REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

4. Medical devices registration software (MDRS) – Pilot program

Company‘s Administrative Profile

Device Specification (Components, Functions, Scope of use…)

Sterilization Method

Certificate of Conformity

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

5. Traceability Records (Article 8):

Suppliers' Required Records

Traceability record (Export 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.

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

6. Vigilance System

- **Article 9:** "Notify the MOH of all unexpected adverse events and side effects resulting from the use of these products".

➔Establishment of procedures for:

- evaluation of products' registration applications and
- traceability of implantable MD

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Achievements

- ✓ **National procedure for the importation of medical devices**

  Defining the minimum safety and quality requirements for the importation of medical devices into the Lebanese market

- ✓ **Guidelines for the evaluation of MD registration applications (draft):** objective criteria for the validation of submitted documents
- ✓ **Procedure for traceability and declaration of adverse events (draft):**

  To identify patients holding a MD if a corrective action is needed and to identify the MD in case of incident.

- ✓ **Establishment of Medical Devices Registration System (MDRS)**
- ✓ **Completion of a training session @ Ansm on evaluation methods of MD registration applications**
- ✓ **Evaluation and validation of suppliers' and products registration applications**

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Achievements

Evaluation and validation of suppliers' and products registration applications:

✓41 companies retrieved "pass key" to the MDRS

✓Products' registration files received from 11 companies

✓134 product registration submittals

✓72 applications examined

- **Providers**
- **PTS**
- **Saramed**
- **Kettaneh**
- **Medicals International**
- **Prime Medicals**
- **Promedz**
- **Benta Trading**
- **Biomedic**
- **Dima Health Care**
- **Intermedic**

REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

The way FORWARD…

<u>Health Technologies Regulation</u>:

- **Comments integration and validation of the documents "Guidelines for the evaluation of MD registration applications" and "Procedure for traceability and declaration of adverse events"**
- **Implementation of the surveillance process**
- **Medical Devices Registration System (MDRS):**

  Modification of the software is under process based on the suppliers' feedback – expected operation in January 2014
- **Training programs**

<u>Health Technologies Management</u>:

Strengthen healthcare institutions capacity in technologies management (Organization of workshops in collaboration with WHO)

Published for discussion on MoPH website (www.moph.gov.lb)

Comments to be sent to projectshealthsystems@gmail.com
before
January 31st, 2014

THANK YOU…