



Guidelines on the implementation of 2D data Matrix Barcode for Pharmaceuticals in Lebanon



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Foreword

Since several years, the Ministry of Public Health has been working on reforming the pharmaceutical sector, in view of improving the quality, safety and efficacy of pharmaceutical products, and to enhance the Health Status in Lebanon.

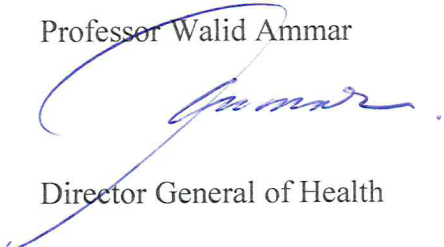
This reform has mainly reached many aspects of this sector: Drugs Registration, Pricing, Marketing Authorization, Good Storage and Distribution Practices, Promotion of the Local Production and Generic Drugs, etc...

At the same time and aligned with MoPH strategy, the National E-Health Program has been working on improving patient safety and on increasing the protection of pharmaceuticals across the supply chain from the point of manufacture to sale to the consumer reducing counterfeited and illegal drugs through the implementation of the 2d data Matrix barcode project allowing the traceability of the pharmaceuticals through a track and trace solution.

In fact, this program falling under the General Directorate of Health, aims to improve the health information systems and establish a national health information repository. Leading E-Government and Digital Transformation projects, this program has been crucial in adopting M-health technology by using different means of communication, such as smart phones and wireless devices to ensure modernization of the administration and to create increased public value with greater openness, transparency, engagement with and trust in government

My deep appreciation goes to Mrs. Lina Abou Mrad and her team for their efforts in improving the e-health national program. This guideline intends to provide all needed requirements in order to establish a track and trace tool that will help build an integrated patient centered system that promotes and sustains the health status of the Lebanese community. Mrs. Abou Mrad's efforts are highly appreciated and her contribution to the improvement of the national e-health system is commendable.

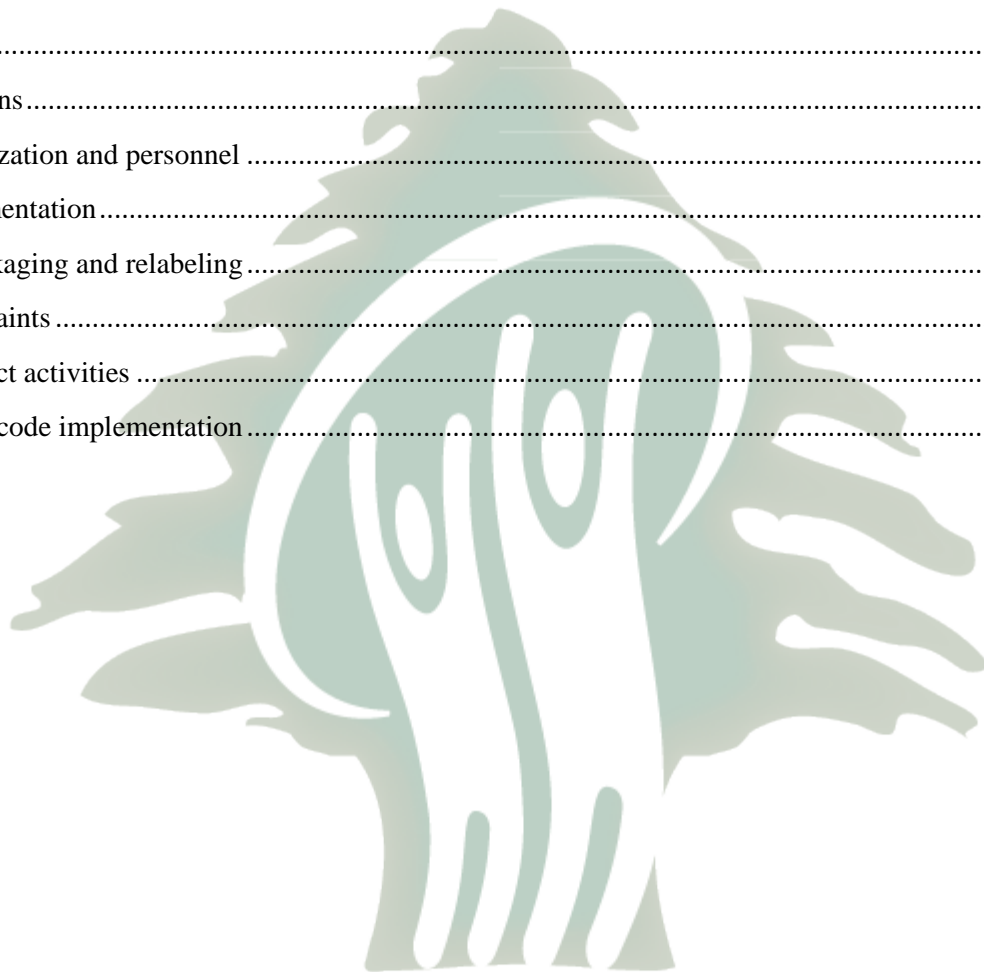
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Director General of Health

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Introduction

With continuing and increasing pressure to reduce healthcare costs and improve patient safety, there is a perpetual need to identify and refine how proven technologies are used to increase the efficiency of supply chain procurement, replenishment and logistics processes and enhance the quality of patient care.

The objective of these guidelines is to ensure safety and quality of pharmaceutical products on the Lebanese market. It sets out appropriate steps to assist in fulfilling the responsibilities of all stakeholders to provide a track and trace tool that will help build an integrated people centered system that promotes and sustains the health status of the Lebanese community.

The Lebanese Ministry of Public Health issues these guidelines, according to the international guidelines of the GS1. The ministry stresses the importance of adhering to it by all parties involved, as relevant to the particular role that they play, believing that the bar-coding technology adds an extra level of patient safety to the medication administration process, reducing medication errors and making the technology increasingly more popular in hospitals and health systems.



Glossary

The definitions provided below apply to the words and sentences used on these guidelines:

2-dimensional symbology

Optically readable symbols that must be examined both vertically and horizontally to read the entire message. Two-dimensional symbols may be one of two types: matrix symbols and multi-row symbols. Two-dimensional symbols have error detection and may include error correction features. ^[1]

Acceptance criteria

An allowance for a small measurement variation between commercial verifiers or operators during barcode verification testing. ^[1]

Barcode

A symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces. ^[1]

Barcode verification

The assessment of the printed quality of a barcode based on ISO/IEC standards using ISO/IEC compliant barcode verifiers. ^[1]

Batch - lot

The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it. ^[1]

Code

- a. A character string used as an abbreviated means of recording or identifying information.
- b. To represent or identify information using a specific symbolic form that can be recognized by a computer. ^[1]

Counterfeit pharmaceutical product

A pharmaceutical product deliberately and fraudulently mislabeled, with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit pharmaceutical products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging. ^[2]

Data

A representation of facts, concepts or instructions in a formalised manner suitable for communication, interpretation or processing by human beings or by automatic means. ^[1]

End user

An organization that employs the GS1 system as a part of its business operations. ^[1]

Expiry date

The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture. ^[2]

GS1

Based in Brussels, Belgium, and Princeton, USA, it is the organization that manages the GS1 system. Its members are GS1 Member Organizations.

GS1 Application Identifier

The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning. ^[1]

GS1 System

The specifications, standards, and guidelines administered by GS1. ^[1]

GTIN-14

The 14-digit GS1 identification key composed of an indicator digit (1-9), GS1 Company Prefix, item reference, and check digit used to identify trade items. ^[1]

Healthcare provider

An organization or facility that delivers healthcare to a subject of care. Corresponds to “care delivery organization”, “healthcare organization”, etc. ^[1]

MediTrack

Track & Trace software developed by MOPH to store the flow of information and track the pharmaceutical products within the supply chain using 2D Matrix barcode for unique identification.

Pharmaceutical product

Any product intended for human use, or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products that may be sold to patients without a prescription, biologicals and vaccines. It does not, however, include medical devices. ^[2]

Product recall

A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency. ^[2]

Quality system

An appropriate infrastructure encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality. ^[2]

Standard operating procedure (SOP)

An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection). ^[2]

Quality

The degree to which a set of inherent characteristics fulfills requirements. ^[3]

Continuous improvement

The recurring activity to increase the ability to fulfill requirements. ^[3]

Corrective actions

Action to eliminate the cause of a detected nonconformity or other undesirable situation. ^[3]

Preventive actions

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. ^[3]

Abbreviations

2D: Two Dimensional

AI: Application Identifier

GTIN: Global Trade Item Number

MOPH: Ministry of Public Health

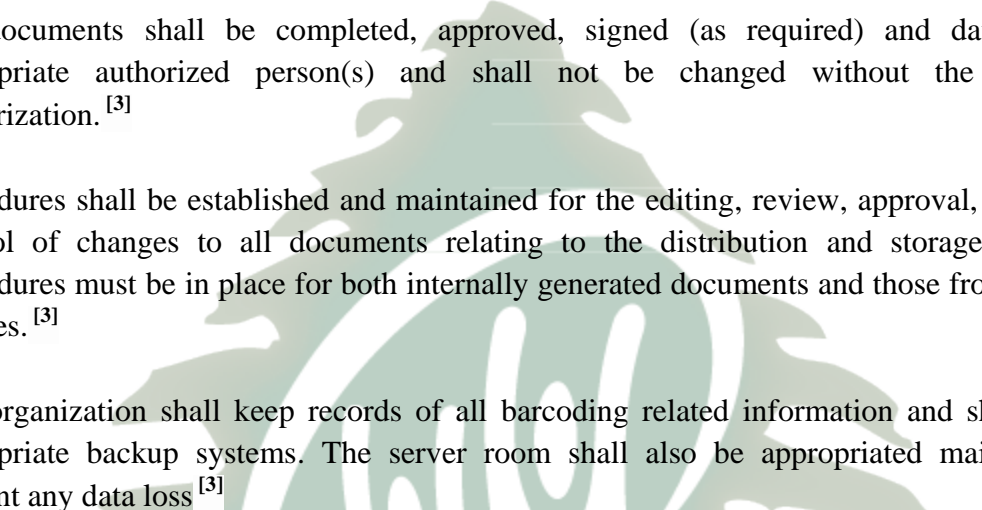
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1. Organization and personnel

- 1.1 There shall be an adequate organizational structure, defined with the aid of an organizational chart that clearly identifies responsibilities, authorities and interrelationships of all personnel.^[2]
- 1.2 Duties and responsibilities shall be clearly defined and understood through documented job descriptions, specifically those involved in the barcoding system. They shall be trained on their respective duties and responsibilities and shall be aware of the relevance and importance of their activities and how they contribute to the achievement of the warehouse quality objectives and policy.^{[2] [3]}
- 1.3 A designated competent pharmacist, who has defined authority and responsibility, shall be appointed within the organization, for ensuring the proper implementation and maintenance of the barcoding system. He shall be accountable on reporting to top management on the performance of the system and any need for improvement.^{[1] [2] [4]}
- 1.4 There must be a sufficient number of personnel able to fulfill all the system's requirements. Personnel training shall be based on written standard operating procedures in accordance with a written training program and they shall be assessed as applicable to evaluate the effectiveness of the actions taken. Appropriate records shall be maintained, including details of subjects covered and participants trained. Delivered trainings shall cover the topic of bar coding, product security, as well as aspects of product identification.^{[1] [2] [3]}
- 1.5 There shall be arrangements in place to ensure that management and involved personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of pharmaceutical products.^[2]

2. Documentation

- 2.1 The organization shall establish appropriate documented procedures and instructions related to all barcoding system. ^[3]
- 2.2 The title, nature and purpose of each document shall be clearly stated. The contents of documents shall be clear and unambiguous. Documents shall be laid out in an orderly fashion and be easy to check. ^[3]
- 2.3 All documents shall be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and shall not be changed without the necessary authorization. ^[3]
- 2.4 Procedures shall be established and maintained for the editing, review, approval, use of and control of changes to all documents relating to the distribution and storage activities. Procedures must be in place for both internally generated documents and those from external sources. ^[3]
- 2.5 The organization shall keep records of all barcoding related information and shall ensure appropriate backup systems. The server room shall also be appropriated maintained to prevent any data loss ^[3]
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3. Repackaging and relabeling

3.1 Repackaging and relabeling of pharmaceutical products shall not be allowed, as these practices may represent a risk to the safety and security of the supply chain.



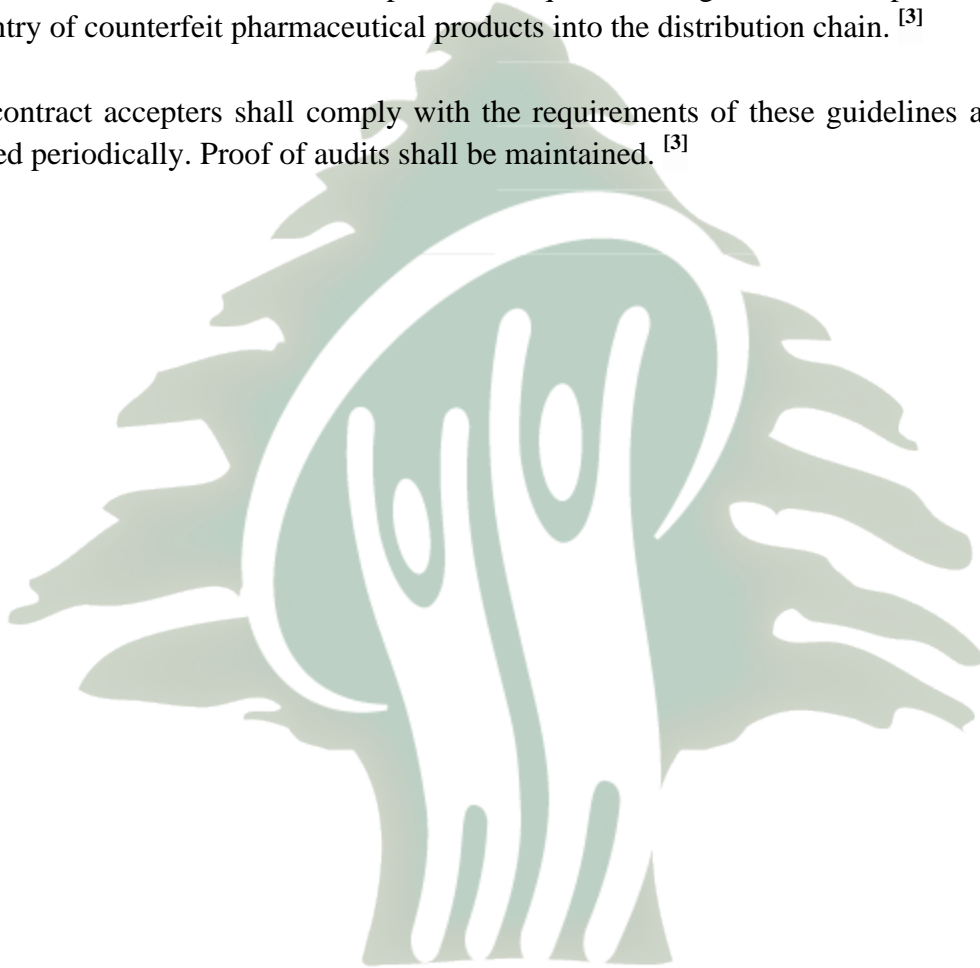
4. Complaints

- 4.1 There shall be a written procedure in place for the handling of complaints specifically those related to the barcoding of the product. ^[3]
- 4.2 Appropriate follow-up action shall be taken after investigation and evaluation of the complaint. There shall be a system in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties. ^{[1][3]}



5. Contract activities

- 5.1 Any activity relating to the barcoding of pharmaceutical products, which is delegated to another entity, shall be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract. ^[3]
- 5.2 The contract shall define the responsibilities of each party. It shall also include responsibilities of the contractor to provide adequate training for involved personnel to avoid the entry of counterfeit pharmaceutical products into the distribution chain. ^[3]
- 5.3 All contract accepters shall comply with the requirements of these guidelines and shall be audited periodically. Proof of audits shall be maintained. ^[3]



6. 2D matrix barcode implementation

6.1 The organization shall ensure that all pharmaceutical products, whether imported or locally manufactured have a 2D barcode according to GS1 standards on their secondary packaging. [5]

The 2D barcode is a square or rectangular shaped barcode containing many small dots and can hold a large amount of information and remain legible even when printed in a small size. This barcode holds a GTIN, a lot number and an expiry date. [4]

6.2 The organization shall be using the 14-digit GTIN format that is unique for each product. The 14 digits indicate the packaging level, the GS1 company prefix and the item reference.

The GS1 AI for GTIN is 01.

The format of the expiration date will be as follows: YYMMDD. The GS1 application identifier for expiration date is 17.

The lot number is up to 20 alphanumeric characters. The application identifier for lot number is 10. [4]

| | | | |
|-------------------------------|-------------------------|----|----|
| Application Identifier | GTIN | | |
| 01 | 0 9501101 53000 3 | | |
| Application Identifier | Expiry Date | | |
| 17 | 14 | 07 | 04 |
| Application Identifier | Batch/Lot Number | | |
| 10 | AB-123 | | |
| Application Identifier | Serial Number | | |
| 21 | X1 → X20 | | |

6.3 The 2D matrix barcode implementation follows the below process:

6.3.1 The organization importing or manufacturing pharmaceutical products submits by email to drugsbarcode@moph.gov.lb all pharmaceutical products related GTIN as per the below format [6]:

| GTIN | MoH Code | Registration # | Brand Name | Strength | Presentation | Form | Agent | Manufacturer | Country |
|------|----------|----------------|------------|----------|--------------|------|-------|--------------|---------|
|------|----------|----------------|------------|----------|--------------|------|-------|--------------|---------|

Pharmaceutical products exempted from the 2D barcode are uniquely the free medical samples and the IV fluids.

6.3.2 MOPH E-health department transfers received data to MediTrack Database, the platform for national barcode system for pharmaceuticals.

6.3.3 MOPH E-health department generates a username and a password, which are automatically submitted to concerned organization importing or manufacturing pharmaceutical products.

6.3.4 The organization importing or manufacturing pharmaceutical products has the possibility to:

- A. Access MOPH MediTrack system and perform required work online
- B. Upload required drugs data to MediTrack system using an excel file
- C. Perform integration with MediTrack system using specific API

A- Access MOPH MediTrack system and perform required work online

- i. The organization importing or manufacturing pharmaceutical products in addition to all recipients of pharmaceutical products shall equip its facility with a continuously backed up computer, Two-dimensional (2D) imager based barcode reader and an internet connection. The barcode reader shall be subject to needed configuration in order to properly function.^{[3] [4] [7]} This configuration, as per GS1 guidelines, ensures the identification of the following special characters: "]d2" at the beginning of the barcode, and the group separator symbol "<GS>" plus the AI identifier.^[8]
- ii. The assigned responsible at the organization importing or manufacturing pharmaceutical products shall access MOPH database and shall work in real time over MediTrack platform on <http://meditrack.moph.gov.lb/moph>
- iii. The assigned responsible shall scan the products barcode on MediTrack.
- iv. The assigned responsible shall complete manually the quantity section noting that upon scanning all other sections will be filled automatically.
- v. Upon distribution, the assigned responsible shall access the platform under Market Movement Section, select destination, insert related information and scan the barcode of the pharmaceutical product, specifying the quantity out.
- vi. The assigned responsible shall save the entries performed and close the page.
- vii. In case of any discrepancy, the assigned responsible shall use the section adjustment movements to adjust any data entry error.

B- Upload required drugs data to MediTrack system using an excel file

- i. The assigned responsible at the organization importing or manufacturing pharmaceutical products shall upload an excel file based on the template as specified in the help Menu in the Movements Upload file specific to each organization type.
- ii. In case of any discrepancy, the assigned responsible is notified automatically to adjust any data entry error.

C- Perform integration with MediTrack system using specific API.

- i. The organization importing or manufacturing pharmaceutical products shall perform systems integration between its own system and MediTrack system following the API compliance guideline specified in the help Menu and specific to each organization type.

6.4 All the recipients of pharmaceutical products shall access the platform, scan the received products and update the database accordingly.

6.5 The organization importing or manufacturing pharmaceutical products shall ensure clear print out of expiry date on the outer package of the pharmaceutical product in a clear way showing MM(Mon)YYYY or MM(Mon).YYYY or MM(Mon)/YYYY or MM(Mon)-YYYY. ^[9]

6.6 The printed GTIN must be preceded by one of the following: (01), GTIN, PC, or CIP, printed expiry preceded by (17) or Expiry date, and Lot/batch preceded by (10) or lot or batch

6.7 The organization shall ensure that the printed information (GTIN, Expiry date, Lot/Batch number) is human readable.

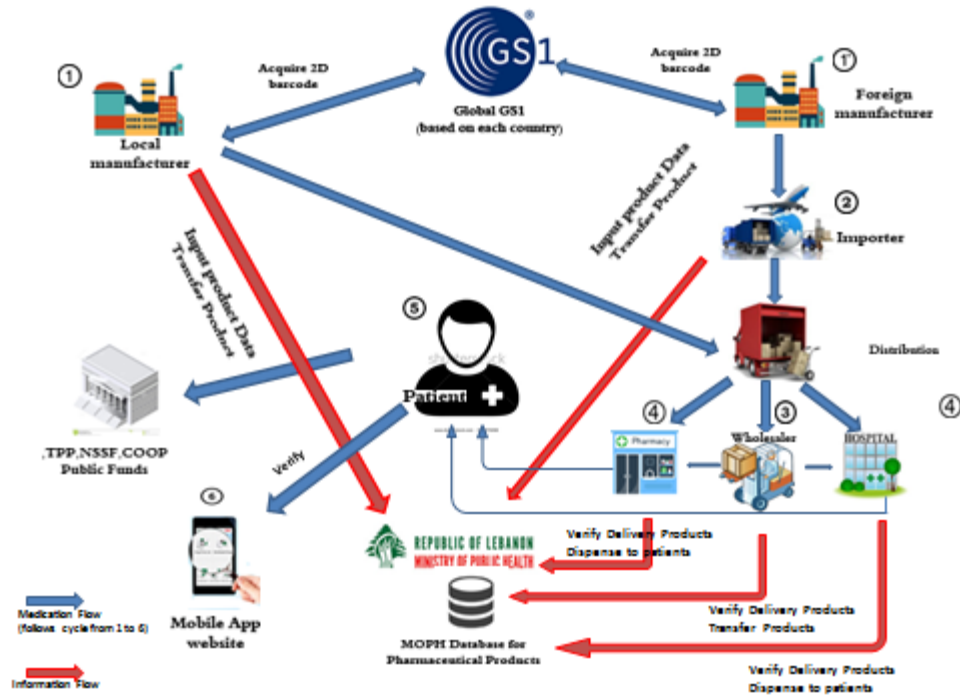


Figure 1 Implementation Workflow

| Flowchart details of The 2D matrix barcode implementation | Responsibilities | | | Associated Documents / Resources |
|--|------------------|-----------------|---------------|--|
| | IMP & MANU | IMP & MANU RESP | MOPH E-health | |
| START | | | | |
| 1.Submit by email to drugsbarcode@moph.gov.lb all pharmaceutical products related GTIN as per the format | E | | | By email drugsbarcode@moph.gov.lb |
| 2.Transfer received data on MediTrack | | | E | MediTrack |
| 3.Generate a user and a password, which are automatically submitted to concerned organization importing or manufacturing pharmaceutical products. | | | E | |
| 4.1.Access MOPH database and perform required work online | E | E | | |
| 4.2.Access MOPH database and upload related excel sheet | | | | |
| 4.3.Perform systems integration | | | | |
| 4.1.1.Equip its facility with a continuously backed up computer, 2D barcode reader and an internet connection. | | | E | MediTrack |
| 4.2.1.Access MOPH database and upload an excel file with the structure as specified in the help section on the section Movements Upload. | | | E | MediTrack |
| 4.3.1.Perform needed systems integration in accordance with the compliance guideline issued by the e-health department. | | | E | MediTrack |
| 4.1.2.Access MOPH database and work live over MediTrack platform. | | | E | MediTrack |
| 4.2.2.Adjust any data entry error. | | | E | MediTrack |
| 4.1.3.Scan the products barcode on MediTrack. | | | E | MediTrack |
| 4.1.4.Complete manually the quantity section noting that upon scanning all other sections will be filled automatically. | | | E | MediTrack |
| 4.1.5.Access the platform under Market Movement Section, Select destination, insert related information and scan the barcode of the pharmaceutical product, specifying the quantity out. | | | E | MediTrack |
| 4.1.6.Save the entries performed and close the page. | | | E | MediTrack |
| 4.1.7.Use the section adjustment movements to adjust any data entry error | | | | MediTrack |
| END | | | E | |

E: Execute

References

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