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*Short communication*

# Principles and methods used in the serialization process of the medicines

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## Introduction

Serialization is the process of assigning a unique identification number on each individual package of the medicine and applying an anti-tampering device in order to implement the measures foreseen in the Directive 2011/62/EU of 8 June 2011 regarding prevention of the entry of falsified medicinal products into the legal supply chain (Council of Europe, 2011).

The Data Matrix system which is globally recognized and approved by the healthcare community, is the most widely used identification system worldwide. 2D Data Matrix codes are composed of unique identification number, European article number (EAN), batch/lot number, expiration date. These codes are generated and applied by the manufacturer and must meet the healthcare regulatory requirements. The Data Matrix serialization system in the supply chain, allows pharmacists to check the authenticity of each individual package when it is dispensed to a patient, by controlling the unique identification number. Scanning the product data matrix automatically and immediately detects duplicate packaging data and activates an alarm in the system alerting the pharmacist that there is a suspicion for a possible falsified product (Haji et al., 2021).

The purpose of this paper is a to describe the equipment used and the activities performed by the packaging department, during the serialization process of the medicines.

## Description of the software and equipment used in the serialization process:

GenCode software is used for serialization (Master data). The software contains data for: production units, article, partner, WO status, SN character, SN status, application identifier, P&V systems, P&V interface version, market, aggregation levels, aggregation labels.

The Master data contains predefined data and materials that are taken over from SAP ERP system. Each material has determined attributes as data.

The packaging process and the process of serialization of the product is performed using *Production unit resource (P&V automatic machine).* Each line on the unit has a Print & Verify System automatic machine for tamper evident labeling, 2D code printing and verification (Pascu et al., 2020).

## The process of serialization

The process of serialization is performed in several stages:

1. Development and approval of a standard for packaging unit (secondary packaging box) for serialization. In accordance with the regulatory requirement for a specific country, the standard for packaging unit is developed and approved.

2. Development and approval of a format/template for serialization. In accordance with the regulatory requirement for a specific country, the format/template (product name, human readable format (HRF) 2D Data Matrix code content, 2D DataMatrix code position, dimensions, print and print inspection, braille position following the technical drawings of the packaging machine manufacturer dimensions) for serialization is approved.

For example, DML_UK_61_28_1.1- where DML is a commonly agreed shortcut format with the data matrix on the left, UK indicates the country for which the format is intended, 61 and 28 are dimensions for box length and width in mm, 1 indicates the position of the data matrix

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for that box size and 1 indicates the first version of the format. HRF is inserted in accordance to the format.
3. Planning the finished product for serialization.
4. Release the work order with serialization.
5. Application of serialization data on each individual package. The process of serialization is performed on the P&V automatic machine: 2D code printing and verification, serialization process and control of tamper evident labeling.

The process of printing 2D code, readable data and their verification includes a determination of critical process parameters, a description of the checks performed, frequency and the quantity of the samples for in process controls.

Methods for performing the tests are pre-determined in the SOPs. All the packaging materials comply with quality specifications, all the operators and maintenance personnel are trained, and adequate SOPs are followed.

Selection of WO-A work order is done by the P&V automatic machine (all available work orders are assigned to the production line from GenCode software for serialization) manually or by scanning the linear code of the work order from the SAP printout (Haji et al., 2021).

The setting of the machine in test mode is used for checking the camera acceptability criterion (minimum C, barcode grading greater than 1.5 is acceptable), for barcode grading and achieving good quality of the print, the predefined position of TE labels from the standard. In the next step, the work order changes its status to “ready for production”. Production file contains production data, T&T counters, start buttons, pause, work order termination (Garcia et al., 2016).

Checking of the critical parameters include check of the printed data, the recording of the left tamper evident label and the recording of the right tamper evident label. Process control during printing data and application on tamper evident labels include check of the rejected boxes in a recipient for rejected boxes on the machine.

T&T counters contain data for all serialization codes in all statuses:

- Assigned - codes that have not been used;
- Commissioned - verified serialization codes
- Product sample codes for analysis;
- Destroyed - destroyed codes that are discarded due to bad quality of the print or lack of TE label;
- Used / destroyed by a printer - codes sent to the printer that are not printed due to printing interruption or printed but not verified;
- Destroyed manually (with a hand scanner)
- Destroyed codes (damaged after verification).

After completing the packaging process, the status of the work order is “finished”. The amount of commissioned serialization codes should be equal to the amount of packaged finished product.
6. Certification and release of a batch of the product

## Results and Report from the process of serialization

The results for all serialization codes for each produced batch of a product are in given in the production report for the process of serialization.

The serialization data are shared to EU HUB, government authorities, distributors, suppliers, and retailers, working to ensure that everyone has access to the information. This is necessary to check the authenticity of the product in each step of the distribution process.

Use of the serialization equipment offers the ability to encode and label large amounts of data on a small area, enabling error detection and correction. This process increases the legibility of the symbol code and allows printing of variable data in the bar code symbol at high speeds in the production lines (Pascu et al., 2020).

Serialization ensures traceability of pharmaceuticals and medical devices and offers improved supply chain security and subsequent end-patient security with the assurance that the product is authentic. In addition, patients receive safe medicines (Council of Europe, 2011).

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