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Short communication

Serialization, defending the medicinal products for human use from counterfeiting

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Introduction

Serialization is a process of placing safety features consisting of: unique identifier and anti-tampering device of each individual drug package, according the national requirements in the territories where serialization is mandatory.

From the aspect of a unique identification, it is a process of generating and applying codes that can be used to uniquely identify each individual pack of medicinal product.

The unique identifier is encoded in a 2D barcode, which is printed on the packaging, as well as human readable data on the same pack. GS-1 global standards are implemented for the data transport via the 2D Data Matrix code. These unique identifiers are stored in the repositories system in the territories where medicinal products are marketed. In EU the repositories system is composed of a central EU HUB, which is connected with national repositories in the marketed territories. EU repositories are set up and managed by a non-profit legal entity (ies) established in the EU by manufacturers and MAHs.

The serialization in EU is mandatory for: prescription medicinal products, medicinal products issued without prescription, and medical products in the extended scope by the member states. RU market as well recognizes serialization as a process of marking of medicinal products with safety features consisted of: unique identification code on each single pack of medicinal product. Serialization in RU is mandatory for all medicinal products for human use.

Serialization principle and implementation in Alkaloid AD — Skopje

Safety features should be placed on an outer (secondary) packaging or to a primary packaging if the medicinal product for human use has no outer packaging. In Alkaloid the Regulatory requirements for serialization and the implementation is followed by multidisciplinary team composing of delegated personnel from QA, QC, Production, Maintenance, IT&T, Sales and Distribution, Logistics, Packaging Development, RA.

The application of the safety features in Alkaloid AD — Skopje is being performed with qualified serialization machines, and a validated computerized system in place. The mechanics of generating a pool of serialization codes, applying them, confirming the used ones, communicating with the HUB is being set-up as an automated process inside the company. This is performed with the validated computerized system in-place for serialization, which is additionally interconnected with the ERP as well as the production machines,

The data printed and verified for EU by the computerized system in place in Alkaloid must contain the following data:

1. DataMatrix contains the following attributes:

- PC (product code) consisting of Global Trade Item Number (GTIN) (ai01) - 14 digits
- SN (serial number) - Unique Serial Number (ai21) - recognized. The need for cooperation and coordination up to 20 alphanumeric characters

  arises in order to ensure high level of public health

- NN (National number) - not a compulsory data,
- date (YYMMDD) (ai17) - 6 digits

2. HRF (human-readable format) is the format that presents the attributes contained in the DataMatrix.

3. ATD (anti-tampering device) is a device for protecting and verifying the medicines packaging from (unwanted) opening.

The data printed and verified by the computerized system for RU market must contain the following data:

1. Data Matrix (2D) matrix code containing the following attributes:

- PC — Global Trade International Number (ai10) — 14 characters (figures)

SN — Individual (unique) Serialized Number (ai21) — 13 characters (figures or alphanumeric characters) Verification Key (ai91) — 4 characters (figures, lower and uppercase Latin letters), crypto code received from the operator of monitoring system Verification Code (ai92) — 44 characters (figures, lower and uppercase Latin letters and special characters, crypto code received from the operator of monitoring system

2. HRF (Human-readable format) presents the following data:

KH: 14 characters (numeric)

CH: 13 characters (numeric) and alphanumeric characters

Cepiis №: maximum 20 figures or alphanumeric characters

- FopeH go: 6 figures (MM YYYY)

3. ATD (anti-tampering device) is optional for RU territories.

4. Aggregation on transport box and on pallet (L3&L5) is mandatory for RU market.

The process of applying the safety features on the pack is a part of the packaging activities carried out in the production departments.

Conclusion

The problem with falsified medicinal products is globally recognized. The need for cooperation and coordination up arises in order to ensure high level of public health protection. Alkaloid successfully implemented the depends serialization requirements for the marketed territories in collaboration with regulatory institutions and other on concerned parties for this common issue in order to assure the imperative — protection and promotion of public health. The process is flexible, which makes it easily Expiry adaptable for any specific market territory requirements.

Alkaloid successfully implemented the serialization requirements in the territories where the serialization is mandatory. The process is empowered and quite flexible, so it can be easily adapted to the specific requirements of the specific market territory requirements.

References

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