KSR service is developed for serving the needs of Pharmaceutical Companies which have serialization needs based on EU/2011/62 (FMD). The smaller Pharmaceutical Companies (MAH) typically don't produce their product themselves at all or they have only a small packaging line with low production volume. They use CMO-s, who produce and package the drugs for them.The number of CMO used by an MAH and the produced drugs (prescription) typically less than 20. For them, a more cost-effective decision instead of an expensive investment is to use a cloud-based service.

In return for a monthly subscription, they get a private cloud service with a secure infrastructure that allows them to fulfil their serial numbering obligations. The service includes the necessary functionality, integration links, and operation.

Furthermore, Konzorcia operates a helpdesk system that provides continuous user support.

The KSR cloud service includes all of the operations that are defined as ISA L4/L5 functionalities:

- Generating serial numbers for packaging,
- Keeping connection within EU HUB according to EMVO,
- Reserving and maintaining serial numbers in a production database.

The users of the system are MAH and CMO organizations, which have their daily serialization tasks: the CMO marks with unique identifiers the packaging of the drugs while the KSR generates the serial numbers and reserve commissioned serial data and finally submit the serials to the EU HUB.

1. THE BASIC KSR OPERATIONS
The following diagram shows the most important functionalities of the KSR system.

**THE BASIC WORKFLOW
OF THE KSR SYSTEM OPERATIONS:**

- The serial number is requested for the daily packaging operations (1,2): both MAH and CMO can ask for a given quantity of serial numbers

- The generated serials are stored in KSR will be downloaded as a file (3) by the CMO through SFTP

- After successful packaging/marking, CMO will reload the commissioned/shipped serials a to KSR (4) through SFTP

- The relevant serials will be submitted to the EU HUB (5) in the appropriate format

- KSR Database will reserve all commissioned serials for 5 years, and provide the necessary maintaining functionalities

2. SERIAL OPERATION DETAILS

2.1 MAH Registration

MAH and its products will be registered in the KSR system with all relevant parameters. (name, address, contact, etc.). MAH will register also all CMO-s who agreed to use the KSR system for serial management. As a consequence, they will get the appropriate user name/password to access the system for daily operations.

2.2 System access

MAH can login into the system, while CMO will access the system through SFTP. MAH will access all CMO data, while CMO can access only the data which is generated for its purposes.

The system supports 2 operation mode: Test and Production mode. During Test mode, MAH and CMO can check daily operation details, which will not be transferred to the production EU HUB environment. MAH can ask for switching to Production mode when all CMO operation is tested and they are working properly.

2.3 Serial generation
(1., 2. operations)

The serial will be generated according to all requirements defined in FMD. Currently, the system supports mainly secondary level serial generation based on GTIN (and PPN). CMO can initiate serial generation request to the daily packaging needs.

The result will be a file of serials with the requested serial numbers which is stored in the appropriate directory (CMO Output)

2.4 Serial download
(3. operation)

CMO can download (through SFTP) the required serial file to the local system, to start daily packaging operations. After a successful marking process, the used serials will be uploaded.

2.5 Upload
(4. operation)

Serial Upload may happen in 2 phase: after Commissioning and after Shipping using EPCIS V1.2 standards. The corresponding file transfer is implemented through SFTP.

Commissioning upload operation will transfer all relevant information which is connected to a specific Batch, including serials and batch parameters. (name, expiration, etc.) Shipping upload will transfer of all serials which are connected the specific shipping operation.

2.6 Change of Serial status
(4.a operation)

After Commissioning the status of the serial can be changed for different purposes (destroyed, stolen, sample). CMO can upload these serial status change to the MAH, to update the Production database. This operation is available only, before Shipping operation.

2.7 Serial Submission to EU HUB
(5. operation)

The production information can be submitted to the EU HUB, according to EMVO protocol requirements This operation will submit all serial batches which were shipped until the submission operation.

Our interface support naturally all other operation s defined by EMVO URS specification.

2.8 Maintain serials for 5 years

Besides reserving the uploading serials for 5 years (or 1 year after expiration _date), the KSR support daily maintenance of archived serial data. If any new status info (counterfeited, stolen, suspected, etc.) is coming through the supply chain, MAH can change the status of the serial, or generate a report for the auditing purposes.