WG IV : Exchange of best practices and hospital pharmacies : Proposal for a system for aggregation of the unique identifier in the hospital setting

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Context

As work is proceeding to prepare for the full entry into force of the FMD it has appeared that the hospital pharmacy sector has some particular problems regarding this matter. This document aims at identifying where possible those problems and providing paths to a possible solution.

Difficulties in implementing the falsified medicines directive for hospital pharmacies

The delegated regulation 2016/161 provides for some special exceptions to cater for the flow of products in the hospital pharmacy. The rationale behind these measures lies in the fact that hospital pharmacies have in general quite large volumes of medicinal products which have to be checked, which is contrasted by the fact that they mostly order directly from the manufacturer, and hence have a lower risk of falsification due to the short supply chain.

A further complication is that most of these institutes in Europe are publicly funded and that the budgetary space is restricted. And argument often heard is that the workforce needed to carry out the decommissioning of the medicinal packages by hand are resources that will not be available to care for patients any more. There is therefore a need to either provide financial backing (which is out of scope of this document) for the new task, or to either simplify the process of decommissioning medicinal products in hospital pharmacy.

The delegated regulation provides in article 23 a possibility for the decommissioning to be carried out by a wholesaler. However, the conditions are quite strict and do not cover a lot of practical situations. Next to this the delegated regulation provides in its considerations a basis for the aggregation of codes, which might be a means to simplify the decommissioning process in the hospital pharmacy. It is to be noted that the solutions described below might be off interest for wholesalers too, as they may allow automation of the supply chain.

Proposed solutions to mitigate the implementation problems in hospital pharmacies

Several solutions have already been discussed in the expert working group. The aim of the following paragraphs are to list and repeat these, and to provide an appreciation of the advantages and disadvantages of each. Furthermore a suggestion is made of measures which should be applied whenever aggregation is used to mitigate the risks that such a simplification of decommissioning entails.

It is to be noted that, except for the cases explicitly provided for in the delegated regulation, the decommissioning is always to be done by the hospital pharmacist under his responsibility. This does not mean that the hospital pharmacy has to scan the package, which is merely a way of transferring the unique number into the computer system, but that he most certainly is responsible for decommissioning the unique number (which he may have obtained in another way) in the national database

- **Simple aggregation** : this is mechanism whereby the individual unique identifiers of packages which are on a certain shipment are combined into one large barcode which allows for the checking out of multiple packages at once.
    - **Advantages :** it is a very simple system which needs only minimal adaptations of the software (at hospital level) it is proven technology that is quite simple to put in place with limited means.
    - **Disadvantages :** there is an increased risk of falsification as the hospital pharmacist has to rely on a supplemental barcode which is not directly linked to the package of the medicinal product. A counterfeiter could thus replace the packages in the shipment, the hospital pharmacist would scan the aggregated barcode in which the unique identifiers might not correspond with the actual boxes which are in the shipment. This simple aggregation requires someone to generate the aggregated barcode, which might either require an adaptation to production lines if it is a manufacturer who provides the aggregated barcode, or the services of a third party provider who scans all barcodes and generates the aggregated barcode. Another disadvantage is that this way of aggregating codes is not in the GS1 standard. While it would be possible to have a GS1 code with one product code and multiple unique numbers, this would not be a standards compliant code and would give technical problems at readout. An change of the GS1 standards would be needed. Furthermore, a 2-D datamatrix can hold about 100 serial numbers at maximum.
- **Digital aggregation** : this process is quite similar to the previous, however rather than encoding the unique codes into one big aggregated barcode the unique codes are encoded into a standardized data file which is then transmitted to the hospital pharmacies. It remains the responsibility of the hospital pharmacy to read out the data file, and to check out the codes, based on the file. The tertiary packaging should then also have to carry have one simple non-aggregated barcode (e.g. GS1 SSCC) which enables reconciliation between the pallet and the data file.

Standardized Data *File : Different standards exists which allow the encoding of a so-called "despatch advice message" in a standardized fashion :*

- *GS1 EANCOM, which is a subset from UN/EDIFACT. This standard is quite old, but heavily used for electronic data exchange in commerce. It offers electronic standards for data exchange from order to cash. Of interest for this discussion is the Despatch advice message (DESADV) which describes a despatched shipment and could be used to encode the despatched medicine's product codes and serial numbers. Transmission of the file from the supplier to the buyer is not highly*

standardized, but the file in question (which is human readable ASCII) could be e.g. even transmitted through email. An example of such an DESADV message in GS2 EANCOM format can be found on https://www.gs1.org/sites/default/files/docs/eancom/s4/desadv.pdf , pages 95-97

- *GS1 XML : This standard is functionally comparable to the EANCOM standard. The main difference is that it uses XML as a basis and is therefore a more "modern" solution for new implementations of electronic data exchange. However, it is up to the stakeholders to use the standard which suites them best. If e.g. a lot of know-how or technical support is available for the EANCOM standard it makes sense to use EANCOM rather than GS1 XML for new projects. An example of a DESADV message in GS1 XML standard can be found on https://www.gs1.org/standards/edi-xml/xml-despatch-advice/3-2-0 , on \instance File\DespatchAdvice.xml*

    - **Advantages** the technology exists and is heavily used in other sectors, the use of data file avoids the physical limitations of the size of the aggregated barcode, and thus the number of packages that can be aggregated is not limited. A disadvantage would be the fact that the data file is even easier to tamper with than a physical printed aggregated barcode and that a secure way of communication is needed in transmitting this sensitive data. The format of the data file should be using existing standards (see above) to avoid having a hospital pharmacy software to cater for different digital formats. The barcode in question could be a GS1 Serial Shipping Container Code (SSCC)
    - **Disadvantages** are that the data file is even easier to tamper with than a physical printed aggregated barcode and that a secure way of communication is needed in transmitting this sensitive data. Hospital pharmacies would have to modify their software as to be able to read and interpret EANCOM or GS1 XML files and submit the extracted unique identifiers to the hub for decommissioning. Hospital and pharma sector have to agree on the level of detail encoded in the file. Packages can still be replaced in the shipment. Either manufacturers would have to make the necessary adaptation to be able to provide the data file, or a third party would have to scan all packages and generate the data file.

- **Digital aggregation supported by the system of repositories** : this system can be regarded as a further evolution of the previous case, where the communication of the data file is realized through the European system of repositories. The hospital pharmacist will scan one simple non-aggregated barcode (e.g. GS1 SSCC) and submit this to the system, the system would then look up which unique identifiers correspond to the non-aggregated barcode and decommission all those unique identifiers.
    - **Advantages** this system would be the most elegant as it does not require the additional big aggregated barcode or transmission of a standardized file which is needed in the previous two solutions. It would also provide a uniform solution for all stakeholders. Risks of tampering with the standardize data file, or errors during the encoding of this data file or big aggregated barcode would be largely avoided. Existing standards (see above) can be used. Hospital pharmacy software needs only minor modifications.
    - **Disadvantages** there is still a risk that packages in the shipment are replaced. This option would require a modification of the system of repositories, beginning with the EMVO blue print model. It is understood that EMVO is no proponent to implement such modifications at this stage, as readiness for February 2019 is the prime

objective and that this extension of the scope might endanger the meeting of this objective. It would also be, as the previous solutions, a solution with a certain cost which in this case would have to be borne by the EMVO and NMVO, and hence would be subject to discussions between stakeholders on the financing model, which would further delay implementation. Manufacturers would have to make the necessary adaptation to be able to upload the data file in the repository. This option would be interesting in the long run, but very difficult to implement in the short run.

- **Addition of an RFID tag to each package (GS1 suggestion)**. In this scenario the data held in the 2-datamatrix would be duplicated in an RFID tag which is included in the package of the medicinal product (inner carton e.g.). RFID had been evaluated as an option for the FMD but was deemed too expensive. Prices have since lowered significantly, making this a more accessible option.
    - **Advantages** would be the ability to scan a complete pallet in one go.
    - **Disadvantages** would be that this is not foreseen in the DR and therefore not clear from a regulatory point of view, it introduces the extra complexity of adding an RFID tag to each package, it requires the hospital pharmacist to buy a scanner capable of scanning a whole pallet, readability in a pallet containing metal packages (aerosol sprays, aluminum blisters) should be tested. Furthermore, this option would add the risk of data theft : as the pallets can be read out at a distance, counterfeiters could harvest codes with an RFID reader if they manage to get close enough to a pallet. Price, although more accessible than 10 years ago, would still be an issue.

Proposed risk mitigation for the above-mentioned solutions

As in the above-mentioned scenario there is no scanning for individual packs it would be necessary for the hospital pharmacist receiving an aggregated code to do some basic checks

- does the number of packages received correspond to the number of packages included in the aggregated barcode
- a representative sample of the shipment should be manually checked as to assure with sufficient degree of certainty that no tampering has taken place with the shipment
- the pharmacist must require that the shipment is packaged in a way that avoids that individual packages can easily be extracted, ex. shrink wrapping, closed tertiary package,…
- In the case that the above checks would fail the shipment must be considered as suspect and can only be delivered to the patient after individual checking of all individual packages. The competent authority must be informed

In case data exchange takes place this exchange should be carried out through secure means. Email, file transfers, etc. should be encrypted, secured and confidential. This exchange should be documented in the contract.

The lower risk in the hospital pharmacy distribution chain is only true when products are sourced directly from the manufacturer. Therefore this simplification through aggregation can only be accepted for packages which are obtained directly from the manufacturer. The subcontracting to a third party for the scanning or the elaboration of a data file should be based on a contract in which responsibilities are clearly stated. Subcontracting can only be to holders of a WDA or MIA authorization.

If national legislation permits, it could be a possibility to deny the use of aggregation to actors who, following inspection e.g., appear not to follow these guidelines.