V1.0

France MVO

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Use of the digital **consolidation process** as applied to hospital pharmacy supply

Recommendations

Introduction

- This document **does not constitute** a position for or against the deployment of a consolidation process.
- It aims above all to **guarantee through technical recommendations** a **sufficient level of quality and security** for those actors who would like to use the consolidation process.
- This document is primarily intended to **accompany the hospital roll-out of the consolidation process**. It therefore concerns hospital establishments, custodians, wholesaler-distributors and manufacturers involved in the implementation of the consolidation process.
- Finally, it should be noted that the application of the consolidation process must be carried out solely on a **voluntary basis**, with the terms and conditions and specificities of application being defined **contractually** between the parties involved.

Overview

1. Hospital context
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3. Description of the issue for all the parties and requirements
4. Legislative and regulatory framework
5. European Commission and NCA (specifically DGOS) working documents
6. The principle of the consolidation process
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1. Hospital context: 5 limiting factors

1. Constrained hospital **budgets**:
   - Lack of resources dedicated to FMD in hospitals
   - Trade-offs to be made between the necessary human resources and IT investments
   - Human resources: recruitment slowdown
   - Consolidation is viewed more acceptable than recruitment from budgetary standpoint

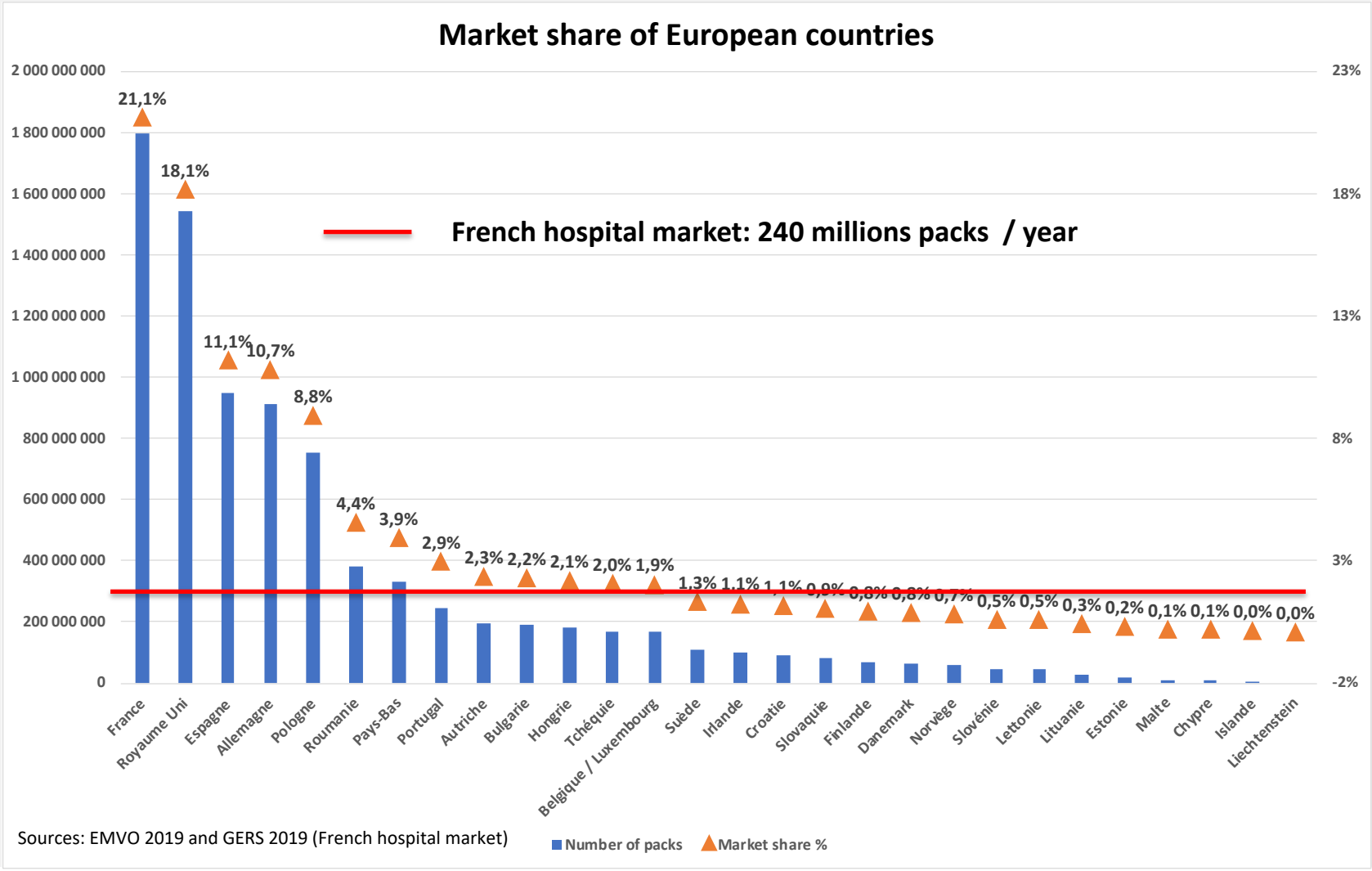
2. **Limited space in the hospital pharmacies** to decommission and restock cartons / pallets that have been opened

3. **Adaptation** to the diversity of software in **pharmaceutical companies** (several existing solutions)

4. **Processing time**:
   - of some logistic units by scanning each pack can be important and incompatible with the dispensation for patients
   - high volumes to be processed upon reception by hospital staff and dispensing by name (if applicable)

5. **Handling and opening** the packs, despite the guarantee of verification they provide, are tasks without any real added value for the staff

1. The French position in the European pharmaceutical market



Sources: EMVO 2019 and GERS 2019 (French hospital market)

2. Manufacturing context: 5 limiting factors

1. Constrained **budgets** of manufacturers:
   - Additional costs related to the equipment of production lines and distribution centres /depositories
   - Trade-offs to be made between the necessary human resources and IT investments
   - Human resources: recruitment slowdown

2. **Limited space in distribution centres** to carry out aggregation and consolidation processes

3. **Adaptation** to the diversity of **hospital software** (several existing solutions)

4. **Processing time**: impact on order preparation time (need to identify each box either by robot or manually)

5. **Handling and opening** cartons are tasks without any real added value for logistics personnel

3. Description of the issue for all parties 1/4

- **Hospitals** are asking for a facilitating process to be put in place.
- **The transmission of the Unique Identifiers** (UI) corresponding to the products delivered facilitates these verification/deactivation operations in hospitals.
- and with the aim of homogenising the technical implementations, the authorities, the various parties in the supply chain and France MVO, have jointly drawn up recommendations based on international standards with the aim of supporting the implementation of this consolidation process in compliance with the security required by European texts.
- **This document summarises these recommendations.**

3. Description of the issue for all parties 2/4

1. **It is essential to harmonise practices / solutions** between manufacturers in order to respond efficiently to hospital needs

2. **Requirements**
   - Regulatory compliance including FMD / DR / Q&A from the European Commission
   - Must be secure
   - Standardisation
   - Guarantee of compatibility with recommendations made by other Member States

3. **General recommendation**
   - Open to all current or future solutions subject to point 2.
   - Define the objectives and obligations in terms of security:
     - Reading the Unique Identifiers (UI)
     - Message authenticity without alteration (integrity)
     - Message intended exclusively for the addressee for whom it was written; message not diverted (confidentiality)

3. Description of the issue for all parties 3/4

4. Possible approaches (“vector / vehicle")
   - EPCIS (Electronic Product Code Information Services): specific message, only dedicated to serialisation / consolidation
   - Evolution of DESADV (Dispatch Advice) message: general message including the information contained in the previous message
   - Alternative value-added platform including information from previous messages

5. Area of responsibility
   - Each party in the transmission chain retains the responsibilities incumbent on them in the light of the regulations in force, which are set out in Chapter 10 "Responsibility"

3. Requirements 4/4

1. **Standardization**
   - Standardization allows the different parties to exchange messages in a predefined common language (syntax and content).
   - Several formats exist, of which the most commonly used are :
     - Edifact (GS1)
     - Edipharm " Electronic Data Interchange Pharm " (EDI)
     - EPCIS (GS1): "Electronic Product Code Information Services" carried by LOGSanté and EALTH
     - Or an alternative that guarantees at least equivalent safety conditions to the previous ones

2. **Security**
   - The data transmitted may be of a confidential nature and the accuracy of the information must be ensured in order to meet pharmaceutical requirement.
   - Security ensures that the data transmitted is not altered or diverted from its original recipient by being intercepted, and that it is received integrally
   - To secure data transmission it is necessary to encrypt the data. Various communication and authentication protocols exist, the most common of which are used in the pharmaceutical sector:
     - SFTP: "Secure File Transfer Protocol".
     - OAuth: "Open Authentication".
     - AS2: " Applicability Statement 2 ".
     - Or an alternative that guarantees at least equivalent safety conditions to the previous ones.
   - In order to have total security of the transmission of information it can be very useful or even indispensable to add a technology that confirms that the data has not been diverted and/or altered (audit trail that cannot be falsified and is verifiable and shared) with the possibility to generate alerts in real time:
     - "Blockchain" technology makes it possible to set up this type of verification.

       https://www.economie.gouv.fr/entreprises/blockchain-definition-avantage-utilisation-application

4. European legislative and regulatory framework

- **The European Directive 2011/32/EU and the European Delegated Regulation 2016/161** provide and frame the implementation of serialization.

- **Consideration 20 of EU Regulation 2016/161** provides for the possibility of using *"an aggregated code allowing the simultaneous verification of several unique identifiers".*

- Question 3.4 of the European Commission's Q&A specifies **the voluntary nature** of the use of aggregated codes.

- **Question 6.6** of the Q&A specifies **the methods** of implementation of facilitated decommissioning in hospitals.

5. Working documents of the European Commission and NCA 1/4

Work Group IV : Implementation of the Falsified Medicines Directive in the Hospital Setting

Working documentation September 2018

- This document **clarifies** the situation regarding the **deactivation of packs at the hospital** and the possibility to use aggregated codes or data files to facilitate the process at the hospital level.

- Hospitals will need to have the necessary **equipment, software, and staff** to decommission unique identifiers individually.

- In order to facilitate **decommissioning at hospital** level, the European Commission is considering the possibility for hospital pharmacists to **decommission specialities** through data files containing the list of packs included in a **shipment** and their individual data (product codes, serial number, expiry date, batch number).

- These files must be linked to the **physical shipment** through an additional bar code. Once the link between the physical shipment and the file has been verified, the hospital pharmacist will be able to use **the list of grouped unique identifiers** to decommission all the packs contained in the shipment without having to scan each pack individually.

5. Working documents of the European Commission and NCA 2/4

Work Group IV : Implementation of the Falsified Medicines Directive in the Hospital Setting

Working documentation September 2018

- These files must **be secure**, confidential and sent separately from the physical shipment by secure processes
- The **responsibility** for checking the safety devices before dispensing to the patient is borne by the pharmacists for hospital pharmacies
- The **verification of the anti tampering device** is also mandatory before dispensing to the patient (no mention is made of an obligation to verify the unique identifier and the anti tampering device at the same time).

5. Working documents of the European Commission and NCA 3/4

NCA (DGOS) Serialisation Methodology Guide (Information Note N° DGOS/PF2/DGS/PP2/2018/196 of 2 August 2018)

- This guide offers the possibility for health care institutions, through voluntary action, to request consolidated codes from custodians or laboratories.

- **The consolidated code:** ***a unique code that groups together all the unique identifiers*** contained in a carton potentially made up of different specialities and affixed to it by the wholesaler.

- This "consolidated code" will also make it possible to integrate the entire hospital pharmacy information system order. All the information related to the order can be transferred to the hospital's information system (IS). »

Note: the notion of "consolidated code" has been used but it should be replaced by "consolidation process" as has been done throughout the reference document to avoid any confusion

5. Working documents of the European Commission and NCA 4/4

NCA (DGOS) Serialisation Methodology Guide (Information Note N° DGOS/PF2/DGS/PP2/2018/196 of 2 August 2018)

- **The digital consolidated code** : the logic is the same as for the consolidated code. The difference lies in the fact that **the unique identifiers are not encoded in a two-dimensional code but in a digital file that is then transmitted to the Hospital Pharmacy**. Thus, "this solution makes it possible to register the identification codes of the packs of medicines in a file that is transmitted electronically to the hospital. »

- **Evolution of contractual measures** : the integration of solutions with consolidated codes must be specifically formalised in the contractual clauses of supply contracts in order to facilitate the acceptance step.

- Note: in the context of Request for Proposal for tenders, the consolidated code should not be mandatory but may provide additional points to ensure competition between pharmaceutical companies.

Note: the concept of "consolidated code" has been used but it should be replaced by "consolidation process" as has been done throughout the reference document in order to avoid confusion.

6. Principle of the consolidation process

- As a reminder, a distinction is made:
  - **Aggregated code ("simple aggregation")** : is generally created at the time of manufacture by the manufacturer, concerns homogeneous shipments (standard carton, pallet of the same batch of the same product)
  - **Consolidation process ("digital aggregation") :** is carried out downstream of the manufacturing process, can be based on the aggregated code if it exists, can be applied to shipments containing different references.
  - **Digital "consolidation",** as understood in these recommendations, consists of **generating a secure electronic message** linked to an order containing the unique identifiers of packs of medicines, in order to enable the **verification and decommission** of several unique identifiers simultaneously and thus facilitate the implementation of serialisation.
  - **The consolidation process**, complemented by a logistics identifier affixed by the wholesalers to the shipment in the form of **a code** (barcode, QR code, etc.), will allow reconciliation between the shipment and the message containing all the unique identifiers (UIs) consolidated from the hospital pharmacy's computer system.
  - This consolidated code can also be integrated into the **hospital pharmacy's IT system** with all the information related to the order (identification number, expiry date, batch number, etc.) which can then be transferred to the hospital's IT system.

7. Positioning of the Serial Shipping Container Code (SSCC) in the process

- For this presentation, the term “order” is used as a supply order issued by the hospital.
- The pharmaceutical company or its designated wholesaler initiates the preparation of the upcoming shipment.
- For the same order there can be several deliveries.
- In the same delivery there can be several shipments and/or several orders.
- Each shipment is identified by an SSCC code.
- The SSCC is an 18 character code with an EAN 128 barcode.
- The SSCC is present on the label of the shipment, but it is also present in the consolidation file (SSCC + Unique Identifiers).
- The SSCC code is the means to achieve an unambiguous match between the physical flow and the received message.
- It may be useful to clearly identify the SSCC code as the code to be scanned.
- It may be useful to specify that the shipment contains serialized packs.
- It is recommended not to mix serialised and non-serialised packs in the same shipment.
- A statement must be affixed to the shipment so that the SSCC code is never obscured or covered by other labels.

8. Consolidation solutions

1. **Content: what is the minimum content of the message (in the DESADV or EPCIS) to be used in the hospital?**
   - Order number
   - Sender
   - Recipient
   - Delivery note with its SSCC hierarchy and the Unique Identifiers (UI) contained in the shipment

2. **The pharmaceutical companies or, where applicable, their designated wholesalers or the wholesalers will check that the file with the unique identifiers corresponds to the physical order dispatched.**

3. **Security (SFTP, AS2 or OAuth)**
   - These standards ensure that the message transfer is secure.

4. **Hospital target - Integration into hospital software allowing decommissioning after a series of actions :**
   - Verification, without decommissioning, of the UI of a few packs chosen according to a methodology making the tested sample representative (military standard type)
   - Checking the anti tampering device (ATD) of the sample
   - Possibility of bulk decommissioning (if heterogeneous) of the entire reception
   - The traceability of the completion of this process must be recorded locally
   - Prior to dispense to the patient, the ATD should be checked at the hospital on all packs
   - The use of robots in the hospital pharmacy is a special case to be taken into account

9. Controls

- **Checks prior to deactivation in the context of France MVS**
  - The pharmaceutical companies or, where applicable, their designated wholesalers or the wholesalers will check that the file sent corresponds to the physical order dispatched.
  - Within the hospital pharmacy, verification, without decommissioning of the UI of a few packs chosen according to a methodology making the tested sample representative (standard military type, square root of the total number of packs). Note that the method makes low volume orders less interesting.
  - Within the hospital pharmacy, verification of the ATD of the sample.

- The hospital pharmacy software will apply the established verification and decommissioning procedures to the Unique Identifiers contained in the consolidation file. It is also recommended, in order to facilitate operations in exceptional cases or in the event of errors, that this software shows at least the following information to the staff carrying out the process :
  - The fields of the Unique Identifier (product code, batch, expiry date, serial number and national code)
  - The name of the product
  - Obligation to check the medicine
  - Foreign medicines
  - Possible errors detected
  - Other relevant information to the host operation (e.g. checks carried out automatically or pending manual validation)

- **Post-deactivation checks in France MVS**
  - Once the codes have been sent, the hospital must wait for the result of the decommissioning by France MVS
  - If alerts are detected, the packs of the medicines concerned must first be located and then steps taken according to the procedures established by the NCAs

10. Responsibility of the end-user

- As serialisation is a pharmaceutical operation, it is up to each party to adapt its quality assurance (QA) approach in order to set up a digital consolidation process, in accordance with existing quality standards.

- As far as end-users are concerned, when they first connect to France MVS, they must validate the rights and obligations of the document ”Terms & conditions of use of the national system" https://www.france-mvo.fr/wp-content/uploads/2019/12/20191212_Contrat-End-User_Final.pdf.

- *5.4. Decommissioning of unique identifiers by End Users can only be done by or after checking and scanning individual packs under their physical control and possession. However, nothing in this Article 5.4 shall prevent an End User, if it is a hospital, from decommissioning unique identifiers by means of Identity files provided by the designated wholesalers, wholesalers or manufacturers who supplied them with the packs concerned, in accordance with the Concerned Recommendations. Mass verifications can only be carried out by End Users for products under their physical control. Where an End User uses or provides Identity Files for the purposes of decommissioning, it must ensure that the process is no less secure than EMVS and must have audit procedures in place to verify the adequacy of its security conditions. The End User shall indemnify the NCP for any loss, damage and claims of any third party suffered by the NCP as a result of the End User's use of the Identity Files to deactivate the unique identifiers, including as a result of any Security Breaches that occur as a result of the End User's use of such Identity Files.*

- *Note: NCP = National Contractual Partner = France MVO*

11. Glossary

- DGOS: « Direction Général de l'Organisation des Soins » (Minister)
- UI: « Unique Identifier»
- SSCC: « Serial Shipment Container Code » (according to GS1 standard)
- XML: « eXtensible Markup Language »
- Data transfer formats
  - Edifact (GS1)
  - Edipharm: « Electronic Data Interchange Pharm » (EDI)
  - EPCIS (GS1): « Electronic Product Code Information Services »
  - DESADV « Despatch Advice »
- Securing
  - AS2: « Applicability Statement 2 »
  - SFTP « Secure File Transfer Protocol »
  - OAuth: « Open Authentification »
- Shipment: refers to a carton or pallet, according to the GS1 definition
- HOSPIT@LIS: integrated & end-to-end IT solution for transporting the DESADV in particular