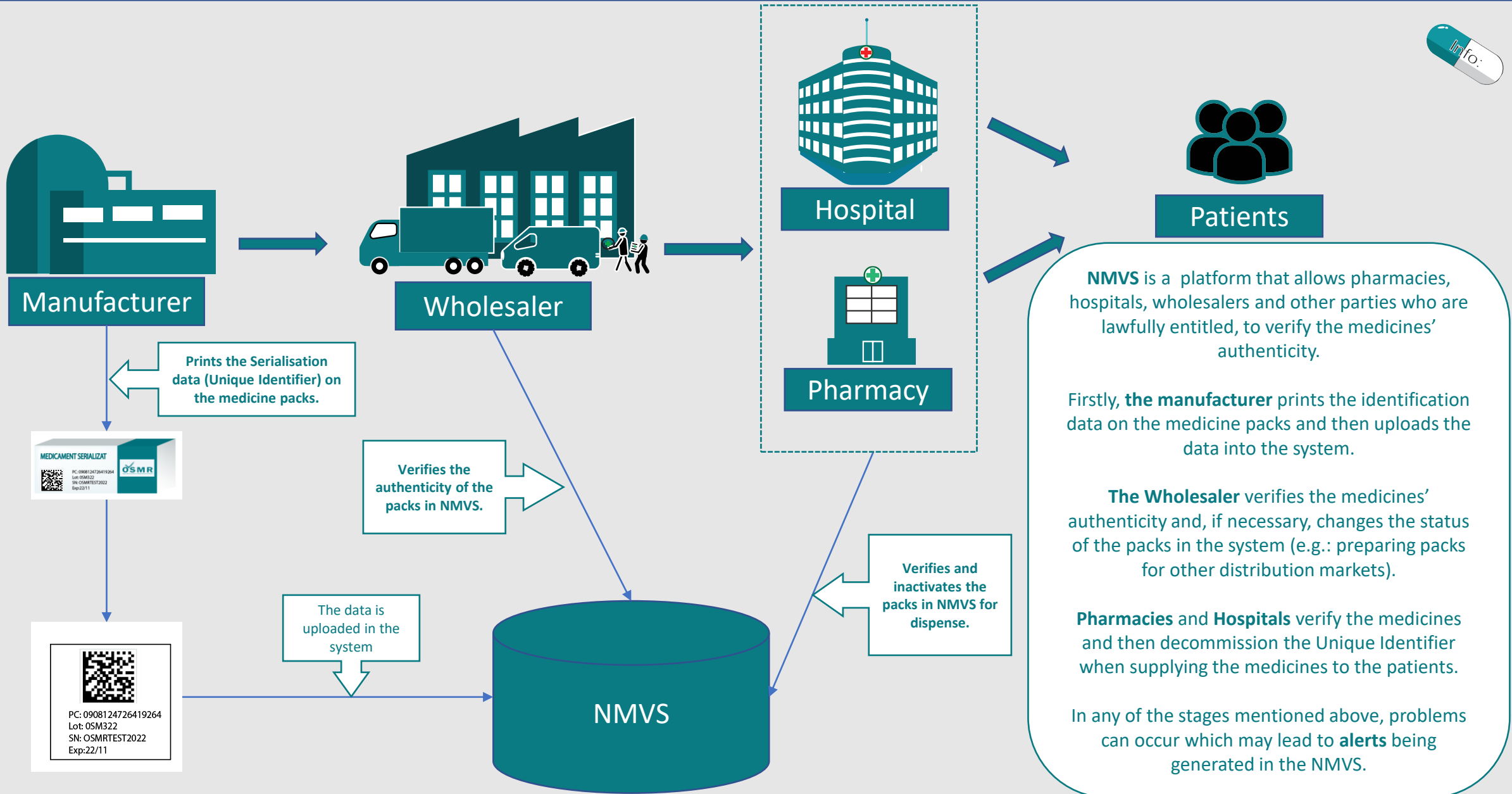
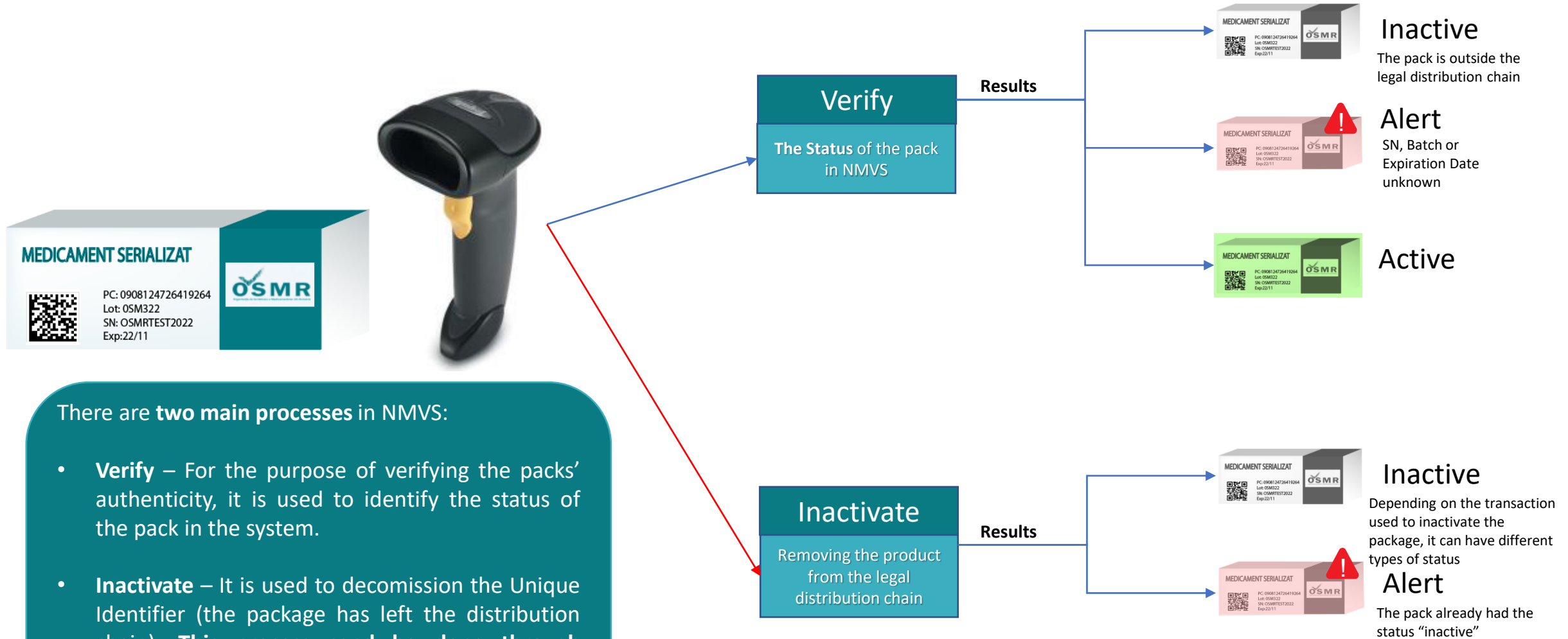




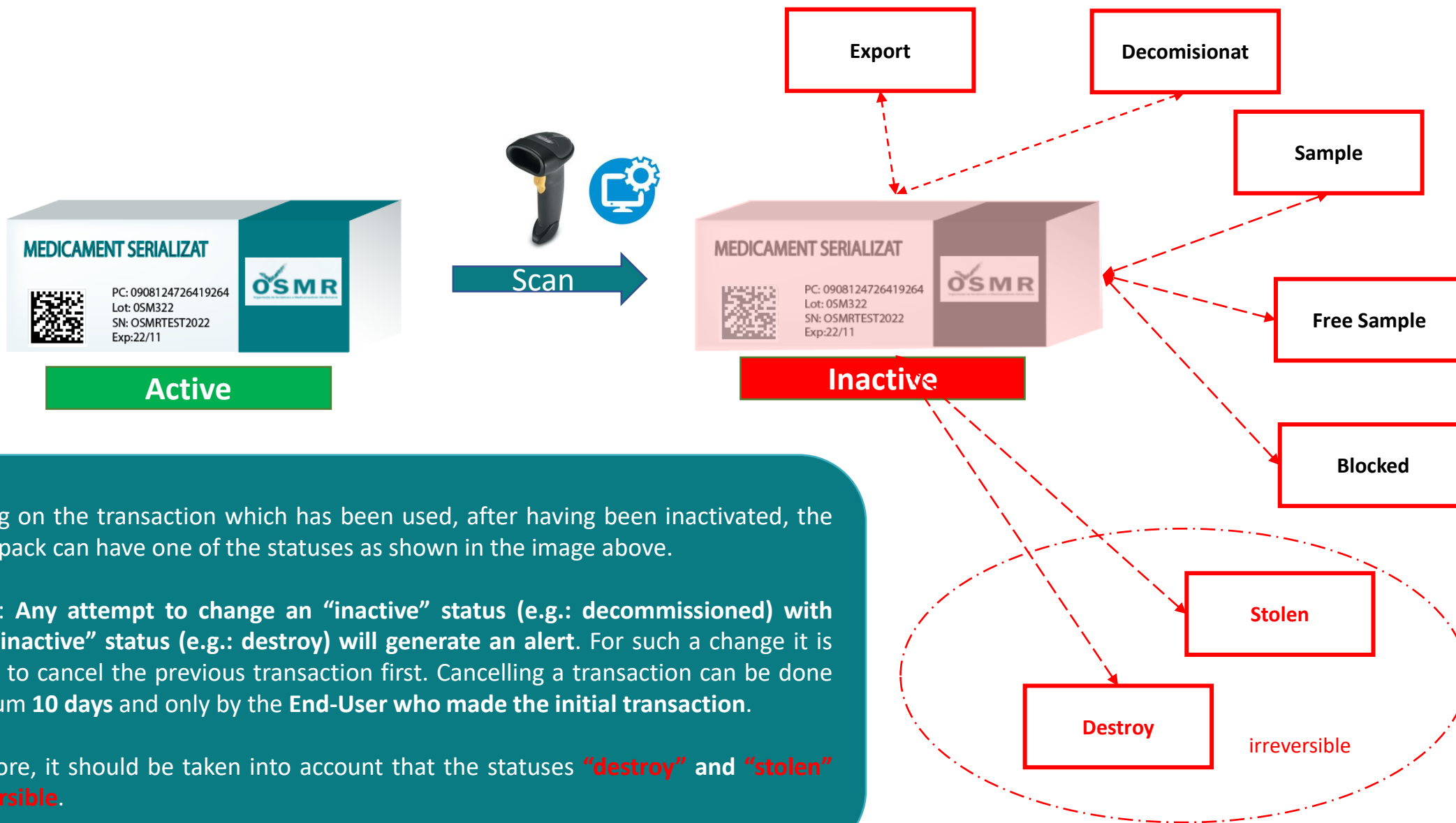
Alerts' Guide





There are **two main processes** in NMVS:

- **Verify** – For the purpose of verifying the packs' authenticity, it is used to identify the status of the pack in the system.
- **Inactivate** – It is used to decommission the Unique Identifier (the package has left the distribution chain). This process can be done through several types of transactions, such as: decommissioning, destroy, export, sample, blocked.

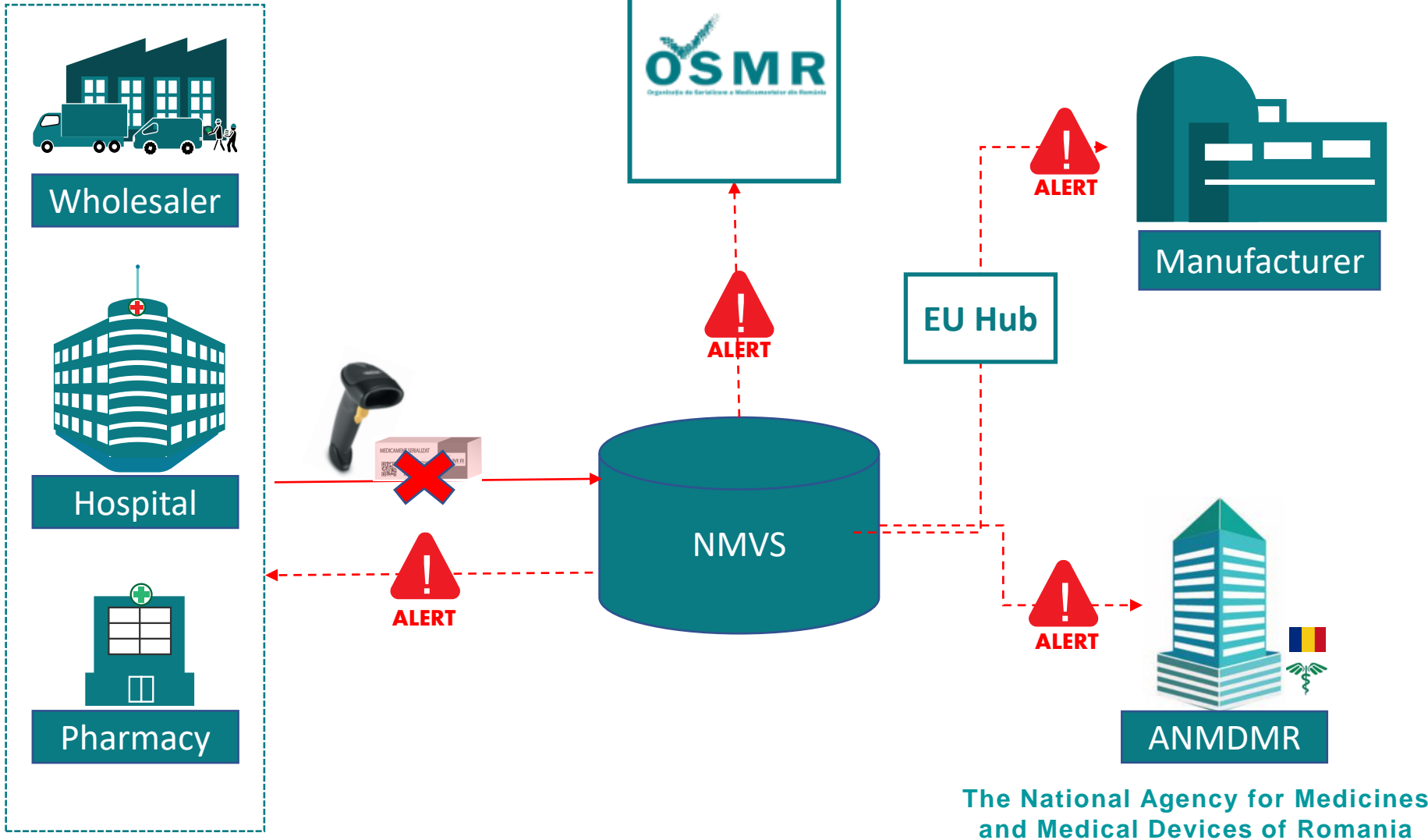


Depending on the transaction which has been used, after having been inactivated, the medicine pack can have one of the statuses as shown in the image above.

Attention: Any attempt to change an “inactive” status (e.g.: decommissioned) with another “inactive” status (e.g.: destroy) will generate an alert. For such a change it is necessary to cancel the previous transaction first. Cancelling a transaction can be done in maximum **10 days** and only by the **End-User who made the initial transaction**.

Furthermore, it should be taken into account that the statuses **“destroy”** and **“stolen”** are **irreversible**.

Alerts' Flow in the NMVS



The alerts raised by the End-Users are simultaneously sent to:

- End-User
- OSMR
- The Medicines' Manufacturer
- Authorities (ANMDMR)
- EU Hub

OSMR is in contact with all the involved parties in this process and is investigating the possible technical causes which led to the alerts being generated.

If, after eliminating all the technical causes, the alerts remain unresolved, OSMR has the legal obligation to inform the Authorities of the respective case.

The National Agency for Medicines and Medical Devices of Romania



NMVS_NC_PC_02 Unknown Serial Number (SN)

This alert is generated when the *Serial Number* is not found in the NMVS.

Possible Cases:

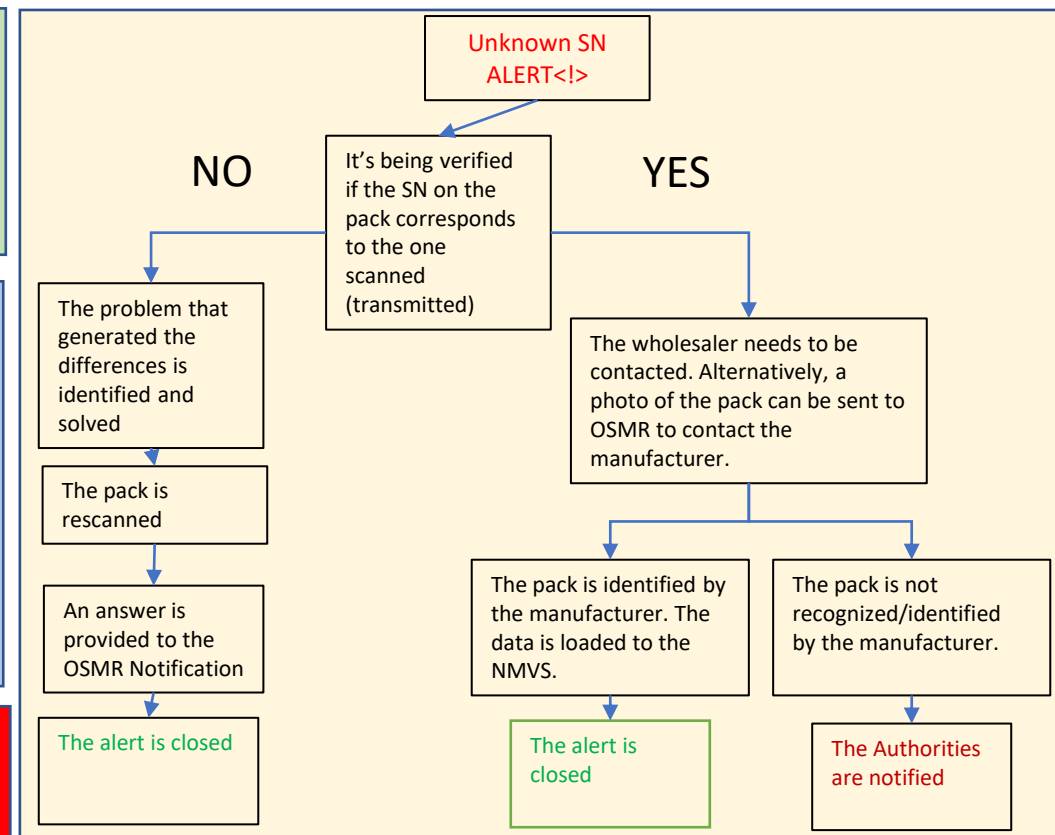
1. Causes found at the manufacturer:

- The Serial Number hasn't been uploaded to the NMVS;
- The uploaded data is incorrect;
- Problems encountered in the printing process (the Data Matrix code or the identification data may contain errors).

2. Causes found at End-Users (hospitals, pharmacies, wholesalers):

- **Scanning error** – The scanner misinterprets the data on the pack.
- **The scanner or the local application are not configured correctly.** These may not interpret correctly the separators contained in the Data Matrix code and erroneously combine the data or transmit it incompletely.
- **Wrong keyboard configuration** – CapsLock key activated, causing the identification data to be transmitted in lowercase letters. Also, setting the keyboard to a language other than the one configured in the application may cause some characters to be misinterpreted.
- **Error when entering the identification data manually.**

3. Suspicion of falsified pack – requires the Authorities' involvement.





NMVS_FE_LOT_03 Failed to find a batch for the given data

This alert is generated when the *Batch Number* is not found in the NMVS.

Possible Causes:

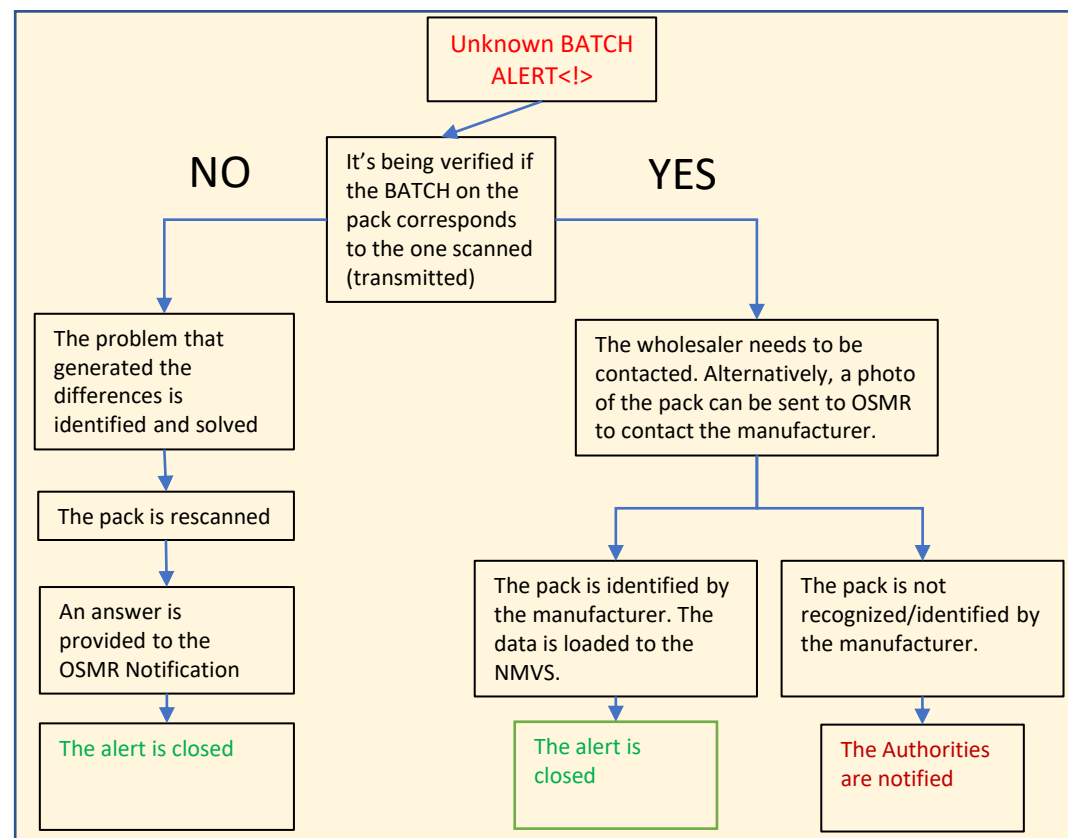
1. Causes found at the manufacturer:

- The BATCH number hasn't been uploaded to the NMVS;
- The uploaded data is incorrect;
- Problems encountered in the printing process (the Data Matrix code or the identification data may contain errors).

2. Causes found at End-Users (hospitals, pharmacies, wholesalers):

- **Scanning error** – The scanner misinterprets the data on the pack.
- **The scanner or the local application are not configured correctly.** These may not interpret correctly the separators contained in the Data Matrix code and erroneously combine the data or transmit it incompletely
- **Wrong keyboard configuration** – CapsLock key activated, causing the identification data to be transmitted in lowercase letters. Also, setting the keyboard to a language other than the one configured in the application may cause some characters to be misinterpreted.
- **Error when entering the identification data manually.**

3. Suspicion of falsified pack – requires the Authorities' involvement.





NMVS_NC_PCK_19 Property is already set on pack

This alert is generated when an attempt is made to inactivate a pack which has already been removed from the distribution chain (e.g.: decommissioning a decommissioned pack)

Possible Causes:

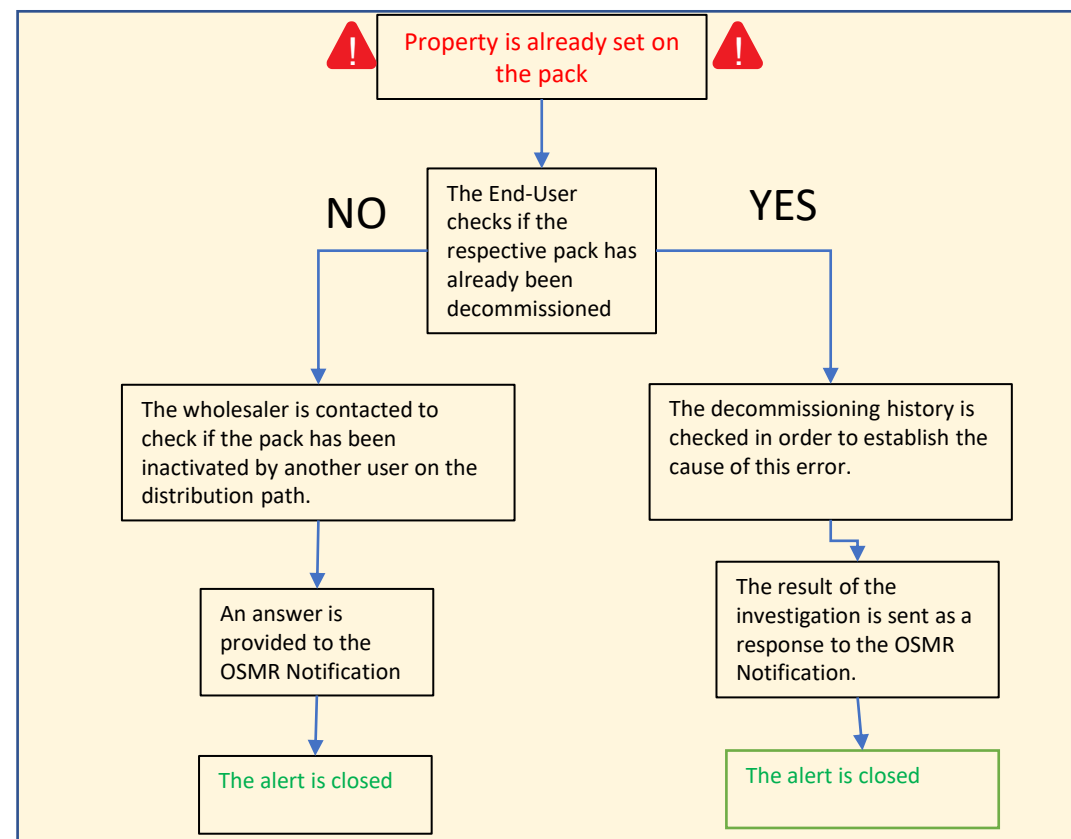
1. Causes found at the manufacturer:

- The same Serial Number has been printed on multiple packs.

2. Causes found at End-Users (hospitals, pharmacies, wholesalers):

- Operator error:** The same pack is passed in front of the scanner, by mistake, several times.
- Fractional sale** – The content of the pack is supplied to several patients and the decommissioning is repeated with each release. According to the Delegated Regulation (EU) 2016/161, Art. 28, in such cases, **the medicine is decommissioned only once, when the pack is first opened.**
- Scanning of packs which should not have been scanned** – E.g.: the pack handed by the patient to the pharmacist in order to be sure that the requested medicine is the correct one.
- Technical error – connection problem.** The system does not confirm in due time the completion of the decommissioning transaction, and the operator repeats it.
- The pack has already been decommissioned by another End-User.** Usually, it is another End-User from the distribution chain of the respective pack (e.g.: wholesaler, another open-circuit pharmacy, another hospital unit, in case it was a transfer).

3. Suspicion of falsified pack – requires the Authorities' involvement.





NMVS_NC_PCK_22 Pack is already inactive

This alert is generated when trying to change the status of a pack which already has an “inactive” status assigned.

E.g.: Decommissioned → Destroy; Sample → Decommissioned;
Decommissioned → Export

Possible Causes:

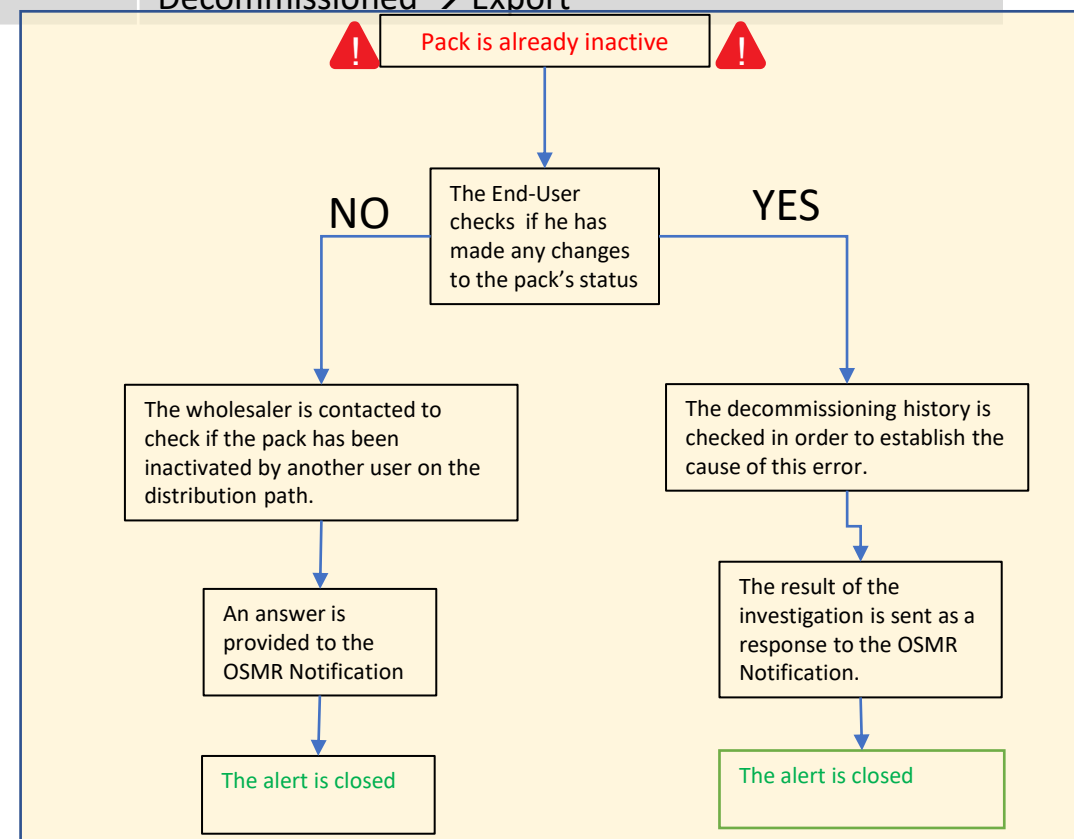
1. Causes found at the manufacturer:

- The same Serial Number has been printed on multiple packs.

2. Causes found at End-Users (hospitals, pharmacies, wholesalers):

- **Operational error:** Attempting to change the status of an inactive pack, without cancelling the previous transaction. For example, when attempting to destroy a pack that has been previously marked as decommissioned.
- **The pack already has a status assigned by another End-User.** Usually, it is another End-User from the distribution chain of the respective pack (e.g.: wholesaler, another open-circuit pharmacy, another hospital unit, in case it was a transfer).

3. Suspicion of falsified pack – requires the Authorities’ involvement.





NMVS_FE_LOT_12 Expiry date does not match the date held in NMVS

This alert is generated when the *Expiry Date* does not coincide with the data uploaded in the NMVS.

Possible Causes:

1. Causes found at the manufacturer:

- The data uploaded in the system is incorrect;
- Problems encountered in the printing process (the Data Matrix code or the identification data may contain errors).

2. Causes found at End-Users (hospitals, pharmacies, wholesalers):

- **Scanning error** – The scanner misinterprets the data on the pack.
- **The scanner or the local application are not configured correctly.** The correct format of the expiry date is **YYMMDD (YearMonthDay)**.
- **Error when entering the identification data manually.** The data format is not respected.

3. Suspicion of falsified pack – requires the Authorities' involvement.

Recommendations for expiry date related alerts:

- The End-User must verify if the expiry date coincides with the expiry date printed on the pack which raised the alert or on another pack from the respective batch.
- It should be noted that the correct format of the expiry date is **YYMMDD (YearMonthDay)**. Also, if the day is not printed on the pack, the last day of the respective month is taken into account.
- In certain cases, instead of the day, the digits "00" are entered on the expiry date field. This is not an error. This "00" marking is interpreted by the system as being the last day of the month.
- If the data on the pack matches the sent data and yet an alert is generated, then the wholesaler should be contacted, to verify if the data uploaded to the NMVS is correct.